


Quality Management Plan Approvals

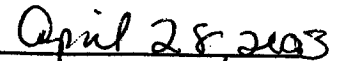
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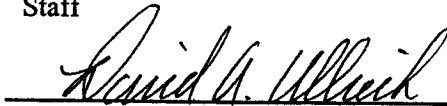
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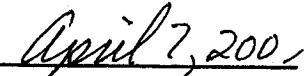
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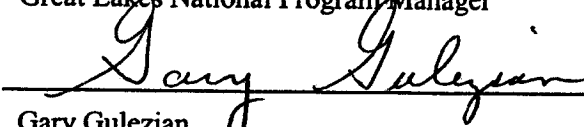


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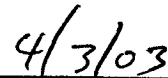


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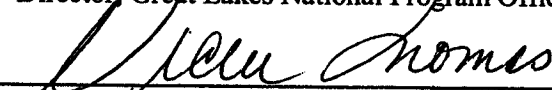
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Gary Gulezian
Director, Great Lakes National Program Office



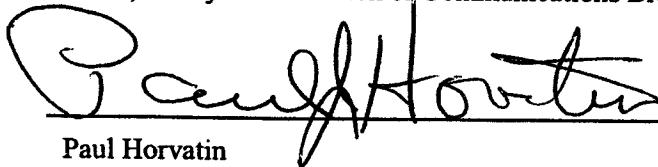
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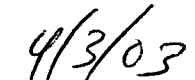
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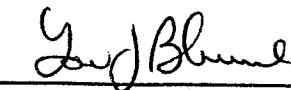
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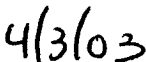
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Quality Manager



Date




UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

APR 28 2003

OFFICE OF
ENVIRONMENTAL INFORMATION

MEMORANDUM

SUBJECT: Approval of the Quality Management Plan for the Great Lakes National Program Office
FROM: 
Naney W. Wentworth
Director, Quality Staff (2811R)
TO: Thomas V. Skinner
Great Lakes National Program Manager

I am pleased to approve the Great Lakes National Program Office Quality Management Plan (QMP) for a period not to exceed five years from the date of this memorandum. This approval was based on a comparison of the QMP to the specifications contained in Chapter 3 of EPA Order 5360 (May 2000), *EPA Quality Manual for Environmental Programs*. Please remember that organizational and/or mission changes may make it necessary for you to revise and resubmit the QMP before the five year approval period expires, per Section 3.2.4 of EPA Order 5360. If there are any questions about the review and approval, please call me at (202) 564-6830.

cc: Louis Blume

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- A. *EPA Quality Manual for Environmental Programs* (EPA Manual 5360 A1) and *Policy and Program Requirements for the Mandatory Agency-wide Quality System* (EPA Order 5360.1 A2)
- B. Great Lakes National Program Office Team Mission Statements
- C. Monthly Quality Assurance Status Tracking Sheet
- D. Great Lakes National Program Office Data Standard: Quality Assurance/Quality Control Codes
- E. Great Lakes National Program Office Information Security Plan
- F. Suggested Quality System Documentation Checklist
- G. *EPA Requirements for Quality Assurance Project Plans* (EPA QA/R-5)
- H. Project Inventory and Approval Form, Grant Agreement
- I. Project Inventory and Approval Form, Interagency Agreement
- J. Quality Assurance Project Plan and Quality Management Plan Checksheets
- K. Examples of GLNPO's Graded Approaches to Quality System Documentation
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- R. Examples of Quality Assurance/Quality Control Analysis Checklists
- S. GLNPO Quality System Documentation Review Procedures and Tracking

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Acknowledgments

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Acronyms and Abbreviations

AOC	Areas Of Concern
ARCS	Assessment and Remediation of Contaminated Sediments
CRT	Communications & Reporting Team
DCM	Document Control Manager
DOE	Department of Energy
DQA	Data Quality Assessment
DQOs	Data Quality Objectives
EICAA	Environmental Information Collection and Assessment Activity
EMIT	Environmental Monitoring & Indicators Team
EPA	Environmental Protection Agency
EPAR	EPA Acquisition Regulations
ERST	Ecological Protection Restoration Team
FAR	Federal Acquisition Regulations
FIPS	Federal Information Processing Standards
FWS	Fish and Wildlife Service
GIS	Geographical Information Systems
GLNPO	Great Lakes National Program Office
HST	Health & Safety Team
IAG	Interagency Agreement
IMS	Information Management Staff
IMDI	Information Management & Data Integration Team
ISP	Information Security Plan
IST	Invasive Species Team
LaMP	Lakewide Management Plans
LAN	Local Area Network
MQOs	Measurement Quality Objectives
MT	Management Team
NIST	National Institute of Standards and Technology
OEI	Office of Environmental Information
OMB	Office of Management and Budget
ORD	Office of Research and Development
P2	Pollution Prevention Team
PBT	Program Planning & Budgeting Team
PE	Performance Evaluation
PTD	Project Tracking Database
QA	Quality Assurance
QAARWP	Quality Assurance Annual Report and Workplan
QMP	Quality Management Plan
QAPP	Quality Assurance Project Plan
QC	Quality Control
QSA	Quality System Audits
RAP	Remedial Action Plans
SART	Sediment Assessment & Remediation Team
SIRMO	Servicing Information Resources Management Officer
SOP	Standard Operating Procedure
SOW	Statement or Scope of Work
TSA	Technical System Audit

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Section 1

Quality Management and Organization

1.1 INTRODUCTION

The Environmental Protection Agency (EPA) Order 5360.1 A2 *Policy and Program Requirements for the Mandatory Agency-wide Quality System*, May 2000 (Appendix A), establishes policy and program requirements for the preparation and implementation of quality management systems. The order requires that all EPA organizational units participate in a centrally managed quality assurance (QA) program. This Agency-wide system management system provides the necessary elements to plan, implement, document, and assess the effectiveness of quality assurance (QA) and quality control (QC) activities applied to environmental programs conducted by or for EPA. The intent is to develop a consistent approach to environmental decisions that ensures the collection of supporting data that are scientifically sound, legally defensible, and of known and documented quality. The Office of Environmental Information's (OEI's) Quality Staff is responsible for developing, coordinating and directing the implementation of the Agency's QA program.

To document adherence to EPA Order 5360.1 A2, EPA requires each organizational unit to develop a quality management plan (QMP) per the specifications in Chapter 3 of EPA's Manual 5360 A1, *EPA Quality Manual for Environmental Programs* (included as Appendix A of this QMP). The QMP is management's statement of the process that will govern the QA activities for a given organization. The QMP defines an organization's QA-related policies, areas of application, roles, responsibilities and authorities of staff, and the management and technical practices that assure that environmental data used to support decisions are:

- of adequate quality and usability for their intended purpose, and
- where necessary, legally and scientifically defensible.

This document defines the Great Lakes National Program Office's (GLNPO's) quality system. GLNPO is a geographically-focused office, whose mission is to lead and coordinate United States efforts to protect and restore the Great Lakes. This QMP is a management tool that describes how GLNPO will plan, implement, document, and assess its quality system to support its mission. The document also communicates the policy and provides guidance on GLNPO's quality management system to all personnel associated with GLNPO. The document has been submitted to GLNPO management and OEI's Quality Staff for review and approval.

Program management is responsible for ensuring that the QMP is implemented. In accordance with policies and procedures established under EPA Order 5360.1 A2 Section 7-b., Program Office Directors and Senior Managers shall:

- (1) ensure that all Program components and programs comply fully with the requirements of the Order;
- (2) ensure that quality management is an identified activity with associated resources adequate to accomplish its program goals and is implemented as prescribed in the organizations approved QMP;
- (3) ensure that the environmental data from environmental programs delegated to State, local, and Tribal governments are of sufficient quantity and adequate quality for their intended use and are used consistent with such intentions;

- (4) ensure that training is available for State, local, and Tribal governments performing environmental programs for EPA in the fundamental concepts and practices of quality management and QA and QC activities that they may be expected by EPA to perform;
- (5) perform periodic assessments of Regional organizations conducting environmental programs to determine the conformance of their mandatory quality system to their approved QMPs and the effectiveness of their implementations;
- (6) ensure that deficiencies highlighted in the assessments are appropriately addressed;
- (7) identify QA and QC training needs for all levels of management and staff and provide for this training; and
- (8) ensure that performance plans for supervisors, senior manager, and appropriate staff contain critical elements that are commensurate with the quality management responsibilities assigned by this Order and the organizations QMP.

This QMP documents GLNPO's quality system to meet these requirements in fulfilling its mission. The QMP is organized in the following ten sections:

- ▶ **Section 1** continues with a description of GLNPO's program, mission, organizational structure, and roles and responsibilities of GLNPO management and staff;
- ▶ **Section 2** describes the components of GLNPO's quality system, including a description of the tools used by GLNPO staff to implement the quality system;
- ▶ **Section 3** provides information regarding personnel qualifications and quality system training requirements;
- ▶ **Section 4** discusses GLNPO's process for procuring items and services and ensuring suppliers provide items and services that are of known and documented quality and meet associated technical requirements;
- ▶ **Section 5** provides information on the control and maintenance of documents and records;
- ▶ **Section 6** discusses GLNPO's process for managing information, including a description of computer hardware and software administration;
- ▶ **Section 7** discusses GLNPO's process for planning environmental projects, including a step-by-step list of questions that project planners can implement during initial stages;
- ▶ **Section 8** discusses GLNPO's implementation of work processes;
- ▶ **Section 9** provides a description of GLNPO's policies and procedures for assessing environmental information collection activities and responding to assessment findings; and
- ▶ **Section 10** discusses GLNPO's ongoing activities towards improving quality throughout the program.

A list of references is included at the end of the document that provides detailed information regarding EPA OEI reference and guidance documents. A number of appendices also are included in the QMP to further communicate GLNPO's quality system to OEI and GLNPO staff and to provide assistance to GLNPO staff and associated agencies and organizations in implementing GLNPO's quality system. For example, Appendix K provides examples of GLNPO's graded approaches to quality system documentation including a quality assurance project plan (QAPP) for a project using secondary data, *Great Lakes Sediment Data Support*, and Appendix L contains a checklist for determining whether peer review is needed for a given environmental information collection and assessment activity (EICAA).

In accordance with the guidance provided in EPA Manual 5360 A1, this QMP is a dynamic document that is subject to change as GLNPO's program progresses. A QMP should represent current activities. This QMP is reviewed annually by the GLNPO Quality Manager to determine if revision is required. In addition, as GLNPO's program progresses in accordance with the continuous improvement philosophy consistent with ISO 9001 (ISO 9001:2000, *Quality Management Systems—Requirements*,

2000), all changes to procedures described in this QMP will be reviewed by the GLNPO Quality Manager to determine if the changes significantly impact the quality objectives of the program. If changes are deemed to be significant, the QMP will be revised accordingly and distributed to the Great Lakes National Program Manager; GLNPO's Director, Branch Chiefs, and Document Control Coordinator; and OEI's Quality Staff.

In accordance with GLNPO's document control procedures, GLNPO's Quality Manager and document control coordinator will maintain controlled copies of this QMP in blue binders (Section 5). These controlled copies will be distributed to GLNPO's Director, Branch Chiefs, and OEI's Quality Staff. GLNPO managers and staff are instructed to locate electronic copies of the QMP on GLNPO's LAN (G:USER/SHARE/ALL/QA/GLNPO QMP/QMP 02) and in hard-copies by obtaining a controlled copy from the Document Control Coordinator.

1.2 QUALITY MANAGEMENT POLICY, GOALS, AND OBJECTIVES

GLNPO's quality management policy focuses on four operating principles: **assistance, flexibility, value-added, and continuous improvement**. GLNPO's quality staff provide assistance to Project Officers (POs) and planners with quality tools necessary to implement their programs. The quality program is flexible with the policy that all QA policies and requirements should provide added value to environmental information collection and assessment activities (EICAAs). GLNPO strives for continuous improvement by constantly evaluating the system to identify problem areas, potential issues of concern, and areas for improvement and then developing and implementing corrective actions to address them. The primary goals and objectives of GLNPO's quality system are implementing projects that are based on sound science and provide information of adequate quality to support the underlying decision. Providing cost effective environmental programs to the taxpayer also is an overarching goal of the quality program.

GLNPO focuses on continuous improvement

The integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

GLNPO is committed to the protection of the Great Lakes system. To accomplish this, a myriad of decisions must be made on the quality of the environment and the health of humans and wildlife. These decisions usually depend on qualitative and quantitative measurements derived from various EICAAs. Decision makers must be able to use these measurements with some level of confidence in order to make informed decisions. **It is the policy of the Great Lakes National Program Office to ensure collected information is of adequate quality for the intended use.** This overarching quality management policy is implemented through a series of policies and practices that are described below.

Policies and Practices

Allocation of appropriate resources

GLNPO management will allocate adequate resources to meet the quality system goals and requirements outlined in this QMP for all EICAAs.

Inclusion of quality management in daily activities

It is GLNPO policy that the quality system must be implemented in daily activities of GLNPO staff. This policy is fostered through training of all GLNPO staff on the quality system philosophy, requirements, tools, and reference documents. In addition, GLNPO's Quality Manager is involved in a supporting role at the project level in many GLNPO-funded EICAA's. GLNPO policy stresses management's responsibility to create an environment in which all personnel contribute to producing high quality products.

Systematic planning

It is GLNPO policy that quality can be achieved only through systematic planning, assessment, and corrective action. Every program supported by GLNPO funds should have clear objectives and a detailed plan to meet these objectives. This is accomplished by employing a thorough systematic planning process at the initiation of any EICAA.

Quality system documentation

It is GLNPO policy that appropriate quality system documentation (such as QAPPs) will be developed for any project which includes EICAAs.

Provision of quality training

GLNPO's quality policy involves training POs and staff on the quality system requirements, available quality implementation tools, and reference and guidance documents to assist them in implementing their programs while meeting GLNPO quality goals and complying with GLNPO's quality system.

EPA recognizes that a "one size fits all" approach to quality requirements will not work due to the variety of projects conducted by EPA and funded entities. Therefore, the implementation of the EPA quality system is based on a **graded approach**. In accordance with EPA's quality system, GLNPO employs a graded approach philosophy throughout all quality system activities. Applying a graded approach means that quality systems for different organizations and programs vary according to the specific objectives and needs of the organization. A graded approach also is applied to quality system documentation.

The level of effort needed to develop and document a quality system should be based on the scope of the program and the nature of the

decision. Similarly, the level of detail for quality documentation of specific projects varies according to the complexity of the work being performed and the intended use of the data. Examples of this philosophy are discussed in this QMP.

GLNPO's Quality System Requirements are commensurate with:

- ▶ Importance of Work
- ▶ Availability of resources
- ▶ Unique needs of organization
- ▶ Consequences of potential decision errors

As mentioned above, GLNPO employs a graded approach to documentation. The Quality Manager, in conjunction with Project Officers, will determine the appropriate level of quality system documentation for each project. In the past, GLNPO has used a four-tiered project category approach (Simes 1989) to determine the detail necessary for QAPPs. These categories have been replaced by the following categories:

- Existing data/Modeling
- Tribal grants
- Sediment assessment
- Consortium grants
- Cluster grants
- Volunteer monitoring
- State Agencies
- Habitat/Ecosystem restoration
- Ambient monitoring and research demonstration
- Pollution prevention and Environmental education
- Repeating projects of similar scope

This QMP encompasses environmental information collection and assessment activities for which GLNPO has lead responsibility, including any contracting and assistance agreements requiring GLNPO funds. However, many agencies (Army Corps of Engineers, Department of Energy, United States Geological Survey, EPA Regions, etc.) and state and private organizations (The Nature Conservancy, The International Joint Commission, The Great Lakes Commission, etc.) cooperate with GLNPO on multiple and recurring projects. In cases where GLNPO is participating in projects which are not the direct responsibility of GLNPO, GLNPO personnel will adhere to the approved quality systems of the lead agency, if consistent with EPA Order 5360.1 A2; otherwise personnel will adhere to GLNPO's quality policy.

1.3 PROGRAM DESCRIPTION

The Great Lakes National Program Office (GLNPO) was created in 1978 to fulfill the United States' obligation under the Great Lakes Water Quality Agreement with Canada. Since inception, additional responsibilities for GLNPO have been defined in Section 118 of the Clean Water Act, Section 112 of the Clean Air Act Amendments, and the Great Lakes Critical Programs Act of 1990. GLNPO is a geographically-focused office, whose mission is to lead and coordinate United States efforts to protect and restore the Great Lakes. GLNPO's responsibilities include:

- overseeing fulfillment of EPA's international commitments under the U.S.-Canada Great Lakes Water Quality Agreement;
- monitoring lake ecosystem indicators;
- managing and providing public access to Great Lakes data;
- helping communities address contaminated sediments in their harbors;
- supporting local protection and restoration of important habitats;
- promoting pollution prevention through activities and projects such as the U.S.-Canada Great Lakes Binational Toxics Strategy and;
- providing assistance for community-based Remedial Action Plans for Areas of Concern and for Lakewide Management Plans.

GLNPO assists Great Lakes partners (including federal, state, tribal, local, educational, and industry organizations) in these areas through technical assistance and coordination, as well as grants, interagency agreements, and contracts.

GLNPO has the primary responsibility for developing policies and coordinating programs relating to the Great Lakes which are both national and international in scope and effect. It functions as a

principal liaison with Canadian federal and provincial governments, the International Joint Commission, other EPA Regions, the EPA Office of International Activities, and the State Department. The Office serves as a focal point of EPA's activities in fulfillment of the Great Lakes Water Quality Agreement. It utilizes the coordinated efforts of contractors, grantees, Regional support staff, and other organizations to generate necessary technical data and reports of findings.

1.3.1 MISSION

The ultimate mission of the Great Lakes National Program Office is to promote the protection and restoration of the chemical, physical, and biological integrity of the Great Lakes ecosystem. GLNPO supports its mission of Great Lakes protection by working towards the following goals:

Chemical Integrity - Reduce toxic substances in the Great Lakes Basin Ecosystem, with an emphasis on persistent bioaccumulative substances, so that all organisms are protected. Over time, these substances will be virtually eliminated. Maintain an appropriate nutrient balance to ensure ecosystem health.

Physical Integrity - Protect and restore the physical integrity of the Great Lakes, including habitats vital for the support of healthy and diverse communities of plants, fish, and other aquatic life and wildlife in the Great Lakes Basin Ecosystem. Protect Great Lakes water as a regional natural resource from diversions and exports.

Biological Integrity - Protect human and biological health. Restore and maintain stable, diverse, and self-sustaining populations of fish and other aquatic life, wildlife, and plants in the Great Lakes Basin Ecosystem, including controlling and eliminating pathogens and preventing the introduction and spread of invasive species to the maximum extent possible, to protect human health, biological health, and economic vitality.

GLNPO, in cooperation with various States, federal agencies, Tribes, and other key partners has developed a Strategic Plan to achieve the above three environmental goals. The Great Lakes Strategy (Great Lakes 2002, A Plan for the New Millennium, April 2002) provides the agenda for Great Lakes Ecosystem management, reducing toxic substances, protecting and restoring important habitats, and protecting human/ecosystem species health. The Strategy was developed cooperatively by the U.S. Policy Committee, a forum of senior-level representatives from federal, state, and tribal natural resource management/environmental protection agencies. The US EPA Great Lakes National Program Manager (also the Region 5 Administrator) chairs this forum. The draft Strategy identifies the major basin-wide environmental issues in the Great Lakes and establishes common goals that the agencies will work toward. It also will help fulfill domestic responsibilities described in the U.S.-Canadian Great Lakes Water Quality Agreement. This strategy includes a fourth goal:

The basin of this international watershed includes two nations, eight U.S. states, a Canadian Province, over forty Tribes and First Nations, and many local governments. Only through a cooperative partnership can we ensure the health of the Great Lakes.

Working Together - Work together as an environmental community to establish effective programs, coordinate authorities and resources, report on progress, and hold forums for information exchange and collective decision-making, so the Great Lakes are protected and the objectives of the Agreement are achieved.

1.3.1.1 *ACCOMPLISHING THE MISSION*

The Great Lakes Strategy identifies the major issues or challenges stakeholders face, establishes major efforts to address these issues, and describes how stakeholders will work together. GLNPO also has established 5 objectives that address issues specific to its role in protecting the Great Lakes ecosystem.

5 Objectives Established By GLNPO to Accomplish its Mission

- ① Integrate Monitoring and Data Interpretation-** The Great Lakes face a multitude of environmental problems with less than adequate funding to address all. Monitoring efforts must be integrated in order to eliminate redundancies and develop consistent methods for reporting and interpretation. GLNPO must be able to interpret and disseminate data and information to a myriad of data users and environmental managers.
- ② Promote Coordinated Efforts -** GLNPO must ensure coordination and communication with cooperators such as EPA Regions, other Federal Agencies, other organizations, States, Tribal Nations, and Canada.
- ③ Enhance Capabilities -** By strengthening and fostering working relationships with other organizations with similar goals, GLNPO serves to enhance its capabilities to meet its mission. This can be accomplished by conducting and coordinating demonstration projects, developing guidance documentation, distributing final interpretative reports, conducting technology transfer, and participating in international symposia.
- ④ Foster Public Understanding -** GLNPO will strive to increase public awareness and knowledge of the Great Lakes through the implementation of its environmental data collection efforts and subsequent interpretive reports, and through implementation of an innovative Great Lakes Public Outreach and Education Program, which would include activities such as the Cities Tours by the R/V Lake Guardian, Environmental Education grants, and publications.
- ⑤ Manage to Reflect Quality -** GLNPO's Quality Management Team implements a value-added quality management system for sound environmental decisions through collection, documentation, assessment, and peer review.

1.3.1.2 SETTING GOALS TO ACCOMPLISH THE MISSION

At the beginning of each fiscal year, GLNPO staff meet to review and assess progress, identify goals for the coming year and outline technical activities to meet those goals. These activities typically include:

- Assessment and mitigation of the effects of air pollution and water pollution introduced into the Great Lakes through monitoring of water, air, biota, and sediments,
- Assessments and mitigation of habitat loss or modification,
- Development of environmental indicators,
- Assessment and mitigation of invasive species,
- Binational coordination,
- Restoration and enhancement of degraded or lost ecological resources,
- Evaluation of the toxicity and extent of contaminated sediments, and
- Pollution prevention.

GLNPO collects environmental measurements in support of these activities. These measurements typically include:

- Sampling and analysis of organics and inorganics in sediments, water, precipitation, air, and wildlife,
- Abundance and concentration surveys of wildlife,
- Toxicity testing using bioassays,
- Testing for physical properties of sediments and water,
- Mapping and landscape characterization techniques through remote sensing platforms,
- Meteorological and physical parameters,
- Surveys regarding utilization of pollution prevention tools,
- Modeling of secondary data, and
- Surveys of environmental education effectiveness.

1.3.2 GLNPO ACTIVITIES AND PROGRAMS

GLNPO has ongoing monitoring programs, conducts special studies to address new impacts of concern, and is involved in several large scale cooperative studies including a lakewide pollutant modeling study, the Lake Michigan Mass Balance Study. Several ongoing activities are summarized below and GLNPO's base monitoring program is discussed in detail in the next section.

Great Lakes Strategy — As discussed above, the strategy is being developed cooperatively by the U.S. Policy Committee and a forum of senior-level representatives from federal, State, and Tribal natural resource management/environmental protection agencies. The draft strategy identifies the major basin-wide environmental issues in the Great Lakes and establishes common goals that the agencies will work toward.

Great Lakes Binational Toxics Strategy (GLBTS) — Signed on April 7, 1997 by the EPA Administrator and the Canadian Minister of the Environment, the strategy has attracted a high level of interest both nationally and internationally. The strategy targets a suite of key chemicals that have impacted the Great Lakes for decades, including mercury, PCBs, and dioxin. The GLBTS has become instrumental in focusing attention on the importance of eliminating persistent, bioaccumulative, toxic substances from the environment.

State of the Lakes Ecosystem Conference (SOLEC) — The fourth biennial SOLEC, held in October 2001, was attended by over 500 people from a wide variety of government and non-government sectors. Objectives for SOLEC include to 1) assess the state of the Great Lakes ecosystem based on accepted indicators; 2) strengthen environmental decision-making and management; 3) inform local decision-makers of Great Lakes environmental issues; and 4) provide a forum for networking among all the Great Lakes stakeholders. SOLEC has brought heightened awareness in the Great Lakes community to several emerging issues, including habitat loss, urban sprawl, and invasive species.

Environmental Indicator Implementation — To be successfully implemented, the SOLEC indicators (discussed above) must be supported by: 1) a commitment to each indicator by at least one stakeholder agency or organization for data collection, analysis, and reporting; 2) coordinated monitoring programs among the stakeholders for cost-effective data collection; and 3) timely reporting through a binational, interactive web site. GLNPO and Environment Canada are organizing the SOLEC efforts in all three areas, but strong cooperation and support of many other agencies and organizations is essential.

Lake Michigan Mass Balance (LMMB) — One of the most extensive studies of a lake ecosystem ever undertaken, the LMMB study is providing important environmental information regarding toxic loadings, transport, and bioaccumulation within the food web. The chemicals under study, PCBs, atrazine, mercury and trans-nonachlor, present a cross-section of important contaminants in the environment. The mathematical mass balance models, the main products of the study, will provide state-of-the-art management scenarios/options for control of toxics in Lake Michigan. Final project results for several components of the study are scheduled for 2001 and 2002.

Binational Consortium to Protect Great Lakes Coastal Wetlands — Over the last several years, Great Lakes coastal wetlands have received increasing attention concerning their quantity and quality. A consortium of Canadian and United States scientists and resource managers has been convened to monitor the size and ecological health of Great Lakes coastal wetlands in order to guide their protection and restoration. The tasks of consortium members over the next two years are 1) to design and validate indicators to assess the ecological integrity of Great Lakes coastal wetlands; 2) to design an implementable, long-term program to monitor Great Lakes coastal wetlands; and, 3) to create, and populate, a binational database accessible to all scientists, decision-makers, and the public.

Invasive Species — In the Great Lakes Basin, over 139 non-indigenous aquatic species have become established since the 1800s. Many of the non-indigenous species have been introduced over the last 4 decades as a result of increased shipping and international trade. Control programs cost millions of dollars annually, and the species are a threat to the ecological and economic value of the Great Lakes. GLNPO participates in regional, national and international efforts to prevent introductions and control the impact of invasive species. Through its grant program, GLNPO is funding programs to investigate control strategies, as well as basin-wide demonstrations of innovative restoration techniques.

Air Deposition — GLNPO, working with Environment Canada, operates the Integrated Atmospheric Deposition Network (IADN), a network of 16 air monitoring stations (5 in the U.S.). The objectives of IADN are to determine concentration trends of priority toxic chemicals, calculate atmospheric loadings (amounts deposited to the lakes), and to supply this information to environmental managers so that appropriate control actions can be pursued. Currently IADN monitors for organochlorine pesticides (including DDT, dieldrin, and chlordane), PCBs, and a suite of polycyclic aromatic hydrocarbons (PAHs). IADN is considered a model for long-term atmospheric deposition monitoring.

Contaminated Sediments — GLNPO provides technical, financial, and field support for state and tribal partners to help solve sediment problems. Recent actions have included remediation efforts involving the

Ottawa River in Toledo, Ohio, and the Fox River in Green Bay, Wisconsin and additional partnership projects are targeted for the Trenton Channel and White Lake in Michigan, and the Minnesota Slip in Duluth, Minnesota. GLNPO also is actively involved in demonstrating the use of treatment technologies as an alternative to landfilling. GLNPO is coordinating efforts with the Army Corps of Engineers to evaluate options for the beneficial reuse of sediments.

Remedial Action Plan Delisting Guidance — Great Lakes Areas of Concern (AOCs) were identified in the 1987 Protocol to the Great Lakes Water Quality Agreement. To date, only one of the 43 identified AOCs has been remediated and formally delisted through the Remedial Action Plan process. A workgroup comprised of federal and state agency staff as well as observers from Canada, the Province of Ontario, and the International Joint Commission (IJC) are developing a guidance document which describes what needs to be accomplished to achieve formal delisting.

1.3.3 BASE MONITORING PROGRAM

GLNPO has primary responsibility within the US for conducting surveillance monitoring of the offshore waters of the Great Lakes. The water quality surveys generally consist of two surveys per year: a spring survey and a summer survey. The spring surveys are designed to collect water quality information during unstratified (isothermal) conditions of the lake, so the survey circuit is planned to move from warmest to coolest waters to ensure that sampling at all sites is conducted before stratification begins. The summer surveys are designed to monitor the quality of each lake during stratified conditions.

Survey activities are conducted onboard EPA's *R/V Lake Guardian*, a former offshore oil field supply vessel. The ship is operated by an onsite ship operations contractor and staffed by GLNPO Chief Scientists, contractors, and grantees. Most of the survey measurements are made onboard the ship, either on the bridge or deck (e.g., meteorological measurements such as wind speed and direction, wave height and direction, air temperature, etc.), by the conductivity/temperature/depth (CTD) probe attached to a sampling device, or in the onboard laboratories (e.g., turbidity, conductivity, pH, etc.). The remaining measurements are made by grantee and contractor staff.

GLNPO attempts to coordinate its spring and summer survey activities with other organizations, such as EPA Regions 2,3, and 5, who are involved in Great Lakes research activities. The goal of this coordination is to maximize sampling activities aboard the *R/V Lake Guardian*. GLNPO offers the vessel for special projects to States, universities, research institutions, agencies, and other organizations. In these cases, GLNPO's Quality Management Team reviews quality system documentation, usually a QAPP or streamlined QAPP that addresses relevant components consistent with the graded approach policy of GLNPO.

GLNPO's quality system tools increase the effectiveness of its monitoring program through:

- documenting and implementing SOPs,
- conducting annual training and readiness reviews,
- coordinating efforts among researchers, State, and Regional staff,
- maintaining, distributing, and implementing a QAPP
- creating real-time electronic data

To support GLNPO's ongoing monitoring programs and other special studies, GLNPO has developed a quality management system to assure environmental information used to support decisions is of adequate quality and usability for their intended purpose.

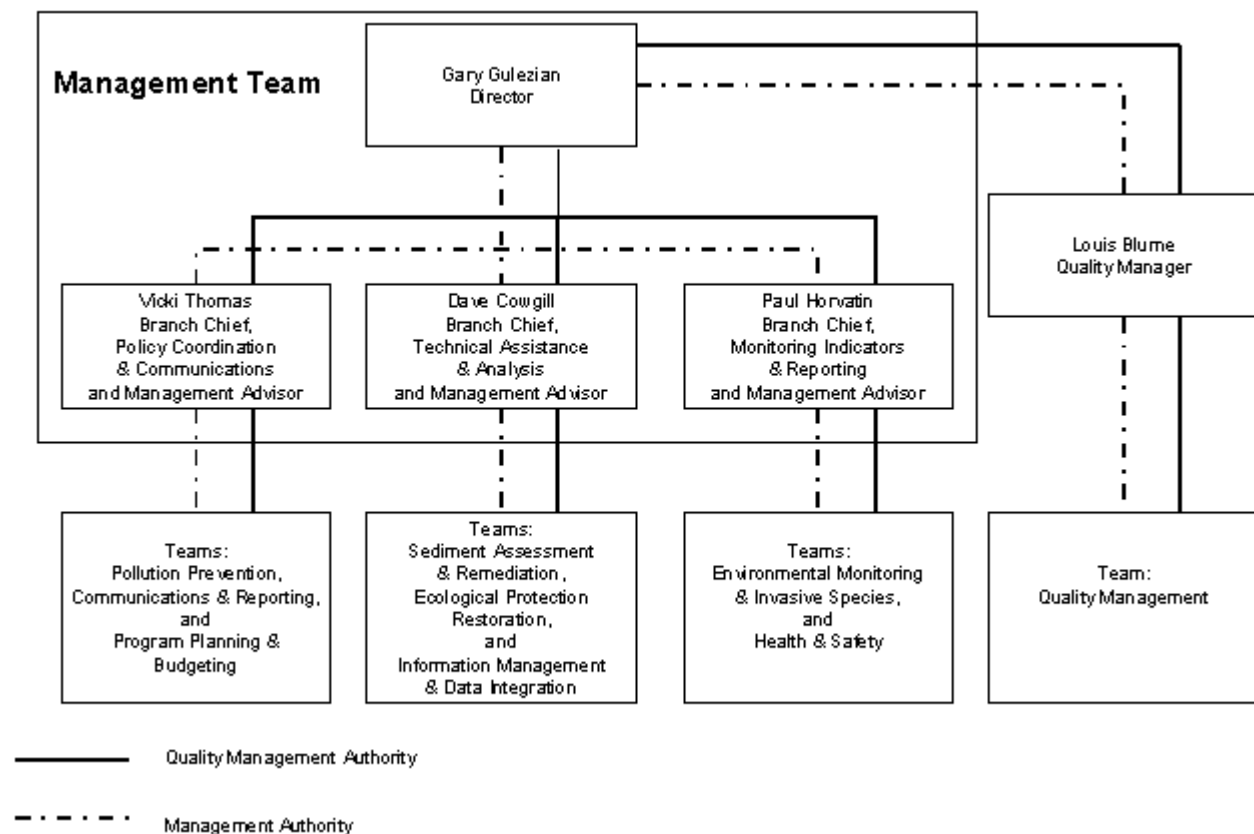
1.4 ORGANIZATION OF THE GREAT LAKES NATIONAL PROGRAM OFFICE

GLNPO is organized into nine teams that specialize in specific areas of interest and expertise for data gathering activities. Each team is comprised of a team leader and staff from GLNPO, and where appropriate, other organizations within EPA (such as Region 5, Region 2, etc). The teams conduct projects, develop products, and provide support to other teams, making teams interdependent and providing for efficiencies. A management team oversees the activities of all other teams. Figure 1.1 represents the

GLNPO staff at all levels are accountable for continuous quality improvement

GLNPO organizational structure. As illustrated, the organization is made up of a Director, Management Advisors, Branch Chiefs, Senior Advisor, Teams, and staff. The following sections describe the functions of the teams and various individuals. The Quality Management Team Leader, the Quality Manager, reports directly to GLNPO's Office Director. GLNPO's Director reports to the Great Lakes National Program Manager, who is also the Region 5 Administrator as dictated by Section 118 of the Clean Water Act, and thus the GLNPO Director is part of Region 5 Senior Management. Therefore, administrative services such as budget development, training, implementation of contracts and grants, and facilities are provided through Region 5. The GLNPO management and staff share responsibility for implementation of GLNPO's quality system.

Figure 1.1: Great Lakes National Program Office Functional Organizational Structure



1.4.1 GLNPO FUNCTIONAL TEAMS

In establishing teams, the following three premises apply: (1) all teams will be established to accomplish tasks identified as Office priorities; (2) each team and its members have responsibility for grant and contract oversight where support resources are essential to achieving team commitments; and (3) in general, PO and grant and contract oversight roles are determined through the teams, the team leader, and the management advisor. These teams are:

- Management Team (MT)
- Ecological Protection and Restoration Team (ERST)
- Sediment Assessment and Remediation Team (SART)
- Information Management and Data Integration Team (IMDI)
- Environmental Monitoring and Indicators Team (EMIT)
- Health and Safety and Environmental Compliance Team (HST)
- Communications and Reporting Team (CRT)
- Pollution Prevention Team (P2)
- Program Planning and Budget Team (PBT)
- Quality Management Team (QMT)

Each team has developed a performance agreement (except for the Management Team and Teamlets), which includes a mission statement. Mission statements of each team are provided in Appendix B. Team leaders are responsible for developing the performance agreements. **Although team leaders suggest and facilitate key people and functions for staff, they are not part of management and do not have supervisory authority.** However, as part of the development of performance agreements, tasks are assigned to key staff and these tasks are finalized with management approvals of the agreements. For this reason, it is important that Team leaders draft performance agreements that are detailed enough to capture staff assignments. Team performance agreements do not cover all GLNPO activities such as: Great Lakes Team activities; developing, publishing and distributing Reports to Congress; LaMP activities; and new activities addressing areas of concern (AOCs). Annually, each team submits a workplan and proposed resources for discussion and approval by GLNPO managers. Team activities for the year are planned based on these approvals. Two “functional areas” also are active and in the future may become teams. They are: Invasive Species and Emerging Issues. These functional areas coordinate grants and contracts and prepare formal and informal reports to management.

The Quality Management Team supports GLNPO’s environmental information collection and assessment activities by providing the necessary resources and tools to assure the collection of data of known and appropriate quality.

The Quality Management Team serves three major functions. First and foremost, the team provides assistance to GLNPO staff and cooperators to assure that studies produce data of adequate quality for the environmental decisions being made. Secondly, the Quality Management Team functions in a role of independent evaluation and oversight to assure adherence to GLNPO quality policy and protocols. Lastly, the Quality Management Team assists in developing documents or products, including policy statements, progress reports, plans, and reports for major data collection activities.

Table 1-1. Major Functions of the Quality Management Team

Function	Description
Provide assistance	<ul style="list-style-type: none"> ▶ Assist in the development of quality system documentation and identification of project quality objectives ▶ Provide tools (software, guidance documents, technical expertise) for the development of quality system products. These include QA project plans, sampling designs, field and laboratory audits, data quality assessments, and QA reports ▶ Provide training on various quality system requirements and concepts, with special emphasis to POs ▶ Assist in defining appropriate project-specific quality system documentation ▶ Provide assistance and guidance in implementing the National Peer Review Policy ▶ Maintain a QA Library ▶ Act as a liaison with EPA Quality Staff (monthly conference calls) for policy information ▶ Attend national/bi-national QA meetings to keep abreast of QA improvements
Evaluation/Oversight	<ul style="list-style-type: none"> ▶ Review and comment on QA project plans within 10 working days of receipt by PO ▶ Assist in implementing data quality and technical systems audits ▶ Conduct data quality assessments ▶ Use QATRACK as an evaluation tool for quality system documentation development (Section 2.6) ▶ Serve as QA chair on various programs ▶ Develop QA reports for major data collection activities ▶ Oversee peer review program
Documentation	<ul style="list-style-type: none"> ▶ Revise GLNPO's QMP every five years or as needed to capture policy changes, submit QMP to Quality Staff, and distribute to GLNPO staff ▶ Write QA Annual Report and Workplan for EPA Quality Staff and GLNPO Staff ▶ Prepare monthly Quality Management Team briefing reports ▶ Maintain a database of peer review and scientific activities. Write a mid-year and annual report ▶ Coordinate development of SOPs for ongoing monitoring projects ▶ Maintain a database for key QA project-level documents ▶ Assist in the development of QA reports for efforts supporting key environmental decisions

1.4.2 KEY PERSONNEL AND ASSOCIATED RESPONSIBILITIES

1.4.2.1 GLNPO DIRECTOR

The Director has overall responsibility for managing GLNPO according to Agency policy and has final authority at the program office level. As noted in EPA Order 5360.1 A2, the direct responsibility for assuring data quality rests with line management. Ultimately, the Director is responsible for establishing QA policy and resolving QA issues which are identified through the Quality Management Team and Quality Staff.

GLNPO's Director fosters a seamless quality management policy by integrating quality activities into daily operations.

Table 1-2. Major Responsibilities of the Director

Function	Description
Management	<ul style="list-style-type: none"> ▶ Serves as Management Team leader ▶ Approves the budget and planning processes ▶ Ensures quality management policy is discussed with GLNPO management and is addressed in individual and team performance agreements
Quality policy establishment	<ul style="list-style-type: none"> ▶ Ensures that GLNPO develops and maintains a current QMP and ensures adherence to the document by GLNPO staff, other EPA offices, and extramural cooperators funded by GLNPO ▶ Establishes policies to ensure that quality management requirements are incorporated in all environmental information collection activities ▶ Ensures that appropriate quality system documentation is developed for all data collection activities in which GLNPO is the project leader and submitted to the QA Manager for review and approval prior to project initiation ▶ Encourages atmosphere where quality management practices are a beneficial and integral part of GLNPO staff daily activities ▶ Recognizes and awards exemplary quality implementation
QA issue resolution	<ul style="list-style-type: none"> ▶ Maintains an active line of communication with the Quality Manager ▶ Facilitates corrective action that may be required by the quality Manager's findings ▶ Ensures that the protocol to address missed requirements in GLNPO assistance agreements (Appendix M) is implemented.

The Director delegates partial responsibility of quality management system development and implementation in accordance to Agency policy to the Branch Chiefs, Team Leaders, and Project Officers. Oversight of the GLNPO quality management program is delegated to the Quality Manager.

1.4.2.2 *BRANCH CHIEFS/MANAGEMENT ADVISORS*

Branch Chiefs and Management Advisors oversee and support the activities of the various GLNPO teams. These individuals serve a dual role: that of supervisor to designated GLNPO staff or Senior Advisors, and that of Management Advisor to designated teams. Because each advisor has specific skills, education, and work experience, advisors are a resource to all teams. The Branch Chief is the delegated manager responsible for data collection and quality management activities of projects occurring within their respective branch. GLNPO's director is the management advisor for the Quality Management Team.

Table 1-3. Major Responsibilities of Branch Chiefs and Management Advisors

Function	Description
Supervision/Management	<ul style="list-style-type: none"> ▶ Supports the team members and assists in obtaining necessary resources ▶ Helps select the team leaders and team members ▶ Advocates the team cause and works to overcome barriers ▶ Ensures that the protocol to address missed requirements in GLNPO assistance agreements (Appendix M) is implemented.
Management of data collection and quality management activities	<ul style="list-style-type: none"> ▶ Ensures that appropriate QA criteria for all projects and tasks are included in operating guidance for all teams in which the Senior Advisor is the Management Advisor ▶ Ensures establishment of data quality acceptance criteria for all projects and tasks conducted by the branch ▶ Ensures that an adequate degree of auditing is performed to determine compliance with quality management requirements ▶ Ensures that deficiencies highlighted in audits are appropriately addressed ▶ Develops quality management-related infrastructure and communications channels ▶ Identifies project-specific quality training needs and provides for required Quality management training ▶ Evaluates QA/QC costs ▶ Reviews and evaluates the quality of outputs generated by each project ▶ Informs the GLNPO Quality Manager of all data collection activities occurring within his/her respective branches ▶ Ensures that all POs understand their quality management responsibilities and that quality is addressed in the position descriptions of all subordinates involved in data collection activities ▶ Ensures that quality management is an identifiable activity with associated resources adequate to accomplish program goals in the development and execution of all projects and tasks, both intramural and extramural, involving environmentally related measurements ▶ Ensures that all projects and tasks involving environmentally related measurements are covered by an appropriate quality system documentation and that the system is implemented

1.4.2.3 TEAM LEADERS

The Team Leader is the person who manages the team, including orchestrating all team activities, calling and facilitating meetings, handling administrative details, and overseeing preparations for reports and presentations. The Team Leader is responsible for preparing Team performance agreements. Ultimately, it is the Team Leader's responsibility to identify team tasks and, through the Supervisor, to assign tasks and provide the means to enable team members to do their work. The Team Leader is the contact point for communication between the team and the rest of the organization, including the management team. The Team Leader position will be periodically reviewed and changes in leaders can occur based on recommendations from the current leader, the team, or the Management Team.

Table 1-4. Role of the Team Leader

Function	Description
Team management	<ul style="list-style-type: none"> Focuses the energies of the team on defining and accomplishing desired outcomes on projects as directed by the Management Team to accomplish an Office priority Strengthens the team and its processes by being careful to see that all matters that involve and affect the team are dealt with by the group, while at the same time avoiding those items or tasks that do not concern the group. (These items are handled by appropriate subgroups or individuals who give feedback on progress and results to the whole team.) Shares information on quality system documentation delinquencies (except for Safety Team) Prepares monthly report and annual workplan (except for Safety Team) Considers quality system implementation in workplan and team discussions Suggests POs to team projects
Communication contact point	<ul style="list-style-type: none"> Helps the team utilize efficient communication processes that provide better information, more technical knowledge, more facts, and more experience for decision-making purposes Routinely updates and briefs the Management Advisor and the Management Team on status of projects, schedules, anticipated road blocks with proposed solutions, budget projections, etc.
Team member encouragement and support	<ul style="list-style-type: none"> Uses group decision making at every appropriate opportunity to earn team member's support for the final product or decision, thus gaining commitment to execute it fully Knows that at times decisions must be made rapidly and cannot wait for group processes; therefore, anticipates these emergencies and establishes procedures with the team for handling them so that action can be taken rapidly with group support Takes primary responsibility for establishing and maintaining a thoroughly supportive atmosphere throughout the team; encourages every member to participate Encourages discovery of alternatives and solutions by protecting team members and their ideas from attack and criticism, so team members feel secure in sharing and exploring a multitude of proposals, ideas, thoughts and opinions

1.4.2.4 TEAM MEMBERS

Although one person in the team will have the formal responsibility of being the Team Leader, each team member shares in the responsibility to accomplish the goals of the team. Whenever a team comes together to trade information, develop strategies, solve problems, or make decisions, every member of the team must share the responsibility for making the meeting as successful as possible. In addition, all GLNPO team members and GLNPO staff are responsible for implementing GLNPO's quality system.

Table 1-5. Responsibilities of Team Members

Function	Description
Accomplishing the goals and purpose of the team	<ul style="list-style-type: none">▶ Team members will consider their participation as a priority responsibility, not an intrusion on their real jobs▶ Team members are responsible for contributing fully to the project as possible, sharing their knowledge and expertise, participating in all team meetings and discussions, even on topics that may be outside their area▶ Team members will carry out their assignments between meetings

An individual may be needed as a team member if they:

- ▶ Possess critical information, knowledge, or expertise pertinent to the subject or project under consideration;
- ▶ Have a stake in the final outcome. That is, this individual will be directly impacted by what is decided, and his/ her commitment is required for successful implementation;
- ▶ Have responsibility for implementing the project;
- ▶ Possess contrary viewpoints that will stimulate discussion, produce critical thinking, and moves the group forward in its thought process; and
- ▶ Need to be a team member because of his or her position in the management structure of the Office.

1.4.2.5 QUALITY MANAGER

The Quality Manager is the delegated manager of the GLNPO quality management program. The main responsibilities of the Quality Manager are overseeing all quality management tasks, ensuring that all personnel understand GLNPO's quality management policy and requirements and that all personnel understand their specific quality management responsibilities. The Quality Manager provides technical support to plan, implement, document, and assess the effectiveness of QA and QC activities associated with GLNPO-funded EICAA's. To facilitate this role, the Quality Manager reviews and approves all quality management products.

Table 1-6. Responsibilities of the Quality Manager

Function	Description
Oversight and management	<ul style="list-style-type: none"> ▶ Interprets Agency quality policy and develops the QA policy for GLNPO in accordance with Agency quality management policies and direction from management ▶ As a quality management advisor, reviews all acquisition packages (grants, cooperative agreements, inter-agency agreements) to determine the necessary QA requirements (the Quality Manager's approval signature is required on all grant acquisition packages to evaluate whether environmental data is collected or used) ▶ Develops quality management budgets ▶ Ensures that all laboratory, field, or office personnel involved in environmental information collection have access to any training or QA information needed to be knowledgeable in QA requirements and protocols ▶ Ensures that audits/reviews are accomplished to assure adherence to approved quality system documentation and to identify deficiencies in QA/QC systems ▶ Ensures that adequate follow-through actions are implemented in response to audit/review findings ▶ Tracks the status of all quality system documentation ▶ Identifies problems and advises on required management-level corrective actions to Director and Management Team ▶ Serves as the program's liaison with Quality Staff ▶ Implements peer review component of quality system
Provision of technical support	<ul style="list-style-type: none"> ▶ Assists staff scientists and project managers in developing quality system documentation and in providing answers to technical questions ▶ Ensures that all environmental information collection activities are covered by appropriate quality system documentation (e.g., QAPPs) ▶ Ensures that sampling and analytical methods for routine operations are well-documented through Standard Operating Procedures (SOPs) ▶ Assists in determining for each project, the need for, type, and frequency of performance evaluation and reference samples. ▶ Assists in solving QA-related problems at the lowest possible organizational level
Development, review and approval of QA products	<ul style="list-style-type: none"> ▶ Develops a QMP and revises it as necessary ▶ Develops a QA Annual Report and Workplan for the GLNPO Director and the Agency's Quality Staff

1.4.2.6 PROJECT OFFICER

The Project Officer (PO) has ultimate responsibility for ensuring GLNPO's quality policy is implemented for all EICAAs under their primary direction. The PO, in consultation with the Quality Management Team, determines the quality system requirements and criteria for scheduled projects based on the intended use of the data. The PO has the responsibility for ensuring that these quality system activities are communicated in the project-specific quality system documentation (e.g. QAPPs). The PO is the key Agency spokesman for the grantee regarding implementation of the quality system. The PO is the principal technical contact for the Agency regarding extramural investments. In general, the PO is the only person who can evaluate the technical content of requested products and accept or reject these products.

GLNPO's Quality Management Team provides "tailor-made" support to assist the Project Officer in implementing appropriate quality system activities.

Table 1-7. Responsibilities of the Project Officer

Function	Description
Coordination of specific project(s) and determination of QA criteria	<ul style="list-style-type: none"> ▶ Develops or assists in the development of project quality objectives ▶ Ensures the submission, review, and approval of appropriate quality system documentation (e.g., QAPP) prior to information collection ▶ Ensures the implementation of approved quality system documentation for the project ▶ Ensures that standard operating procedures (SOPs) for each data collection operation are reviewed and approved ▶ Implements systematic planning for all environmental information collection activities ▶ Reviews project products for adherence to QA goals ▶ Adheres to Agency peer review policy ▶ Alerts management and Quality Management Team when a grantee or contractor is not producing acceptable deliverables ▶ Arranges for performance evaluation samples or reference samples (when applicable) in consultation with the quality manager ▶ Arranges and conducting audits ▶ Ensures that required corrective actions are implemented ▶ Reports data quality problems to the Quality Manager. ▶ Reviews the quality system documentation with project staff, and for extramural projects, with extramural organization's QA representative and principal investigator ▶ Ensures that the protocol to address missed requirements in GLNPO assistance agreements (Appendix M) is implemented.

In some cases, GLNPO will fund programs in other EPA Regions and a Project Officer will be identified from Region staff. This individual will be responsible for the quality management activities listed above as required in the Region's QMP. However, the GLNPO Quality Manager and other staff will have an opportunity to review quality management material as defined in Section 1.2

1.4.2.7 *PRINCIPAL INVESTIGATOR*

The principal investigator (both intramural and extramural) is responsible for adhering to guidance and protocol specified in the quality system documentation when carrying out tasks for GLNPO-funded EICAAs.

Table 1-8. Responsibilities of the Principal Investigator

Function	Description
Adherence to quality system documentation	<ul style="list-style-type: none"> ▶ Prepares quality system documentation, in accordance with EPA Order 5630.1 A2 and grant specifications, and submits it to GLNPO PO for review and approval prior to information collection activities ▶ Negotiates data quality requirements with the PO and appropriate QA representatives ▶ Trains staff in the requirements of the quality system documentation and in the evaluation of QC measurements ▶ Develops standard operating procedures (SOPs) and implements good laboratory practices ▶ Verifies that all required quality management activities were performed and that measurement quality standards were met as required in the quality system documentation ▶ Follows all manufacturer's specifications for utilized instrumentation ▶ Performs and documents preventative maintenance ▶ Documents deviations from established procedures and methods ▶ Reports all problems and corrective actions to the PO ▶ Prepares quarterly reports and final project report in addition to other deliverable requirements in the grant/contract

1.5 WORKING WITH EPA REGIONS AND STATES

In implementing EICAA's to achieve its mission, GLNPO works cooperatively with EPA Regions 2, 3, and 5, as well as eight Great Lakes States (Pennsylvania, New York, Ohio, Indiana, Michigan, Illinois, Minnesota, and Wisconsin). The Regions, as well as some of the Great Lakes States, have developed and implemented quality systems specific to their EICAAs. Implementation of the quality systems may not be similar; however, comparability of data collected from each organization is of prime importance. Before cooperative projects are implemented, Regions, States, and programs participating in the project will have an opportunity to review quality system documentation. The PO has the responsibility of reviewing the quality system documentation from a technical perspective. GLNPO will distribute this QMP to Regions with which it frequently cooperates for review and comment. GLNPO also will review quality system documentation from the respective Regions, States, and other organizations to gain an understanding of their quality policy requirements.

GLNPO will work with States to develop and implement an approved quality system through review and approval of a quality management plan. If a State has a GLNPO-approved quality system, then GLNPO will assist the State with review of quality system documentation but will defer to the State for approval of the documentation. To date, Wisconsin is the only state to develop a GLNPO-approved QMP; however, additional states are in the process of developing QMPs.

1.6 HISTORY OF QUALITY MANAGEMENT AT GLNPO AND ORGANIZATIONAL ACCEPTANCE

GLNPO initiated an independent quality management program in 1992, previously operating under the Region 5 QA Program. Since 1992, GLNPO's program has matured and now governs a wide variety of environmental information collection activities. Currently, for all base monitoring program activities that derive key environmental data for the Government Performance and Results Act (GPRA), GLNPO has established sampling and analytical protocols that are documented in a retrievable and publicly-available format. GLNPO also has developed a database that includes a common data dictionary and sufficient management controls that provide for data collection storage and reporting. In aggregate, GLNPO's quality system provides for ensuring quality data collection for decisions based in sound science.

GLNPO's efforts over the next five years will emphasize maintaining the current program, as documented in this QMP, as well as institutionalizing the use of our data systems and standards. Further, GLNPO hopes to work with the many external stakeholders implementing the new Agency QA Order which is consistent with the International Standard 9000 (2000), that provides for all our partners to implement consistent quality management systems.

Section 2

Quality System Components

GLNPO must implement a quality management program that provides the management and technical practices to ensure that environmental information used to support Agency decisions are of adequate quality and usability for their intended purpose. GLNPO uses a wide variety of quality management practices and tools to implement its quality system including:

- quality management plans,
- project quality objectives and systematic planning,
- quality system documentation,
- standard operating procedures,
- training,
- tracking EICAAs,
- quality management team monthly reports to management,
- Director review of quality system implementation at the branch level, and
- GLNPO's annual report and workplan.

2.1 QUALITY MANAGEMENT PLANS

This QMP serves to document GLNPO's quality system and also to communicate the quality system to all GLNPO staff. The QMP is developed for use by all GLNPO staff, as detailed in Section 1. This QMP is approved by the GLNPO Director, Branch Chiefs, Team Leaders, and a Quality Staff representative. Staff also will be encouraged to use the QMP as a reference in support of EICAA's. When funding EICAA's through States, Regions, or other organizations, GLNPO may require development of a QMP for important or long-term projects that support a critical environmental decision.

2.2 PROJECT QUALITY OBJECTIVES AND SYSTEMATIC PLANNING

A crucial component of GLNPO's quality system is up-front systematic planning. Although projects vary greatly in scope and importance, each should be started in essentially the same way —by determining the level of quality required and by planning accordingly. Consistent with GLNPO's graded approach, the level of quality required will be determined by evaluating the importance of the activity, available resources, the unique needs of the organization, and the consequences of potential decision errors. A systematic planning process is used to facilitate the planning of data collection activities. It asks the data user to focus their planning efforts by specifying: 1) the use of the data (the decision), 2) the decision criteria, and 3) an acceptable probability threshold for making an incorrect decision based on the data. The process should:

- ▶ establish a common language to be shared by decision makers, technical personnel, and statisticians in their discussion of program objectives and data quality;
- ▶ provide a mechanism to pare down a multitude of objectives into major critical questions;
- ▶ facilitate the development of clear statements of program objectives and constraints which will optimize data collection plans; and
- ▶ provide a logical structure within which an iterative process of guidance, design, and feedback may be accomplished efficiently and cost effectively.

Systematic planning must be a normal part of the project planning process and must be accomplished based on cost-effectiveness and realistic capabilities of the measurement process. A

detailed step-by-step process for planning is included in Section 7, that can be used to assist POs and planners with planning effective EICAAs and complying with GLNPO's systematic planning requirements.

One approach that can be used for systematic planning is the Data Quality Objective process as described in EPA's document *Guidance for the Data Quality Objective Process*, EPA QA/G-4, August 2000. Generally, the data quality objectives (DQOs) are statements of the overall maximum uncertainty associated with the measurement system and the population that the data users are willing to accept in the results derived from the EICAA. It is the responsibility of the GLNPO PO to define this allowable uncertainty and develop DQOs with the principal investigators and cooperators. When a formal DQO document is required, it will be reviewed and approved by the Quality Manager and the Branch Chief. Training software on the DQO process also can be acquired from Quality Staff: *Decision Errors Feasibility Trials (DEFT)* is an updated version of earlier software that assists in the implementation of the DQO process.

A formal systematic planning document must be prepared for EICAAs that meet any of the following criteria:

- ✓ EICAAs in support of EPA regulations or enforcement;
- ✓ Long term monitoring programs at numerous sites throughout the Great Lakes and surrounding basin;
- ✓ EICAAs that provide a basis for significant environmental decisions (relative to the importance of the decision);
- ✓ EICAAs longer than two years; and
- ✓ Any EICAA for which the Director deems it necessary.

Other projects that do not meet these criteria will require less formal documentation and should include the following information:

- ✓ definition of the objectives of the study and why environmental data are needed;
- ✓ definition of the quality of the data needed in order to meet the objectives (acceptable uncertainty);
- ✓ time and resource constraints of the project and how it affects data quality;
- ✓ identification of the possible errors that may arise during the data collection process; and
- ✓ the calculations, statistical or otherwise, that will be performed on the data in order to arrive at a result.

A systematic planning process assists the user in defining the purpose for the EICAA and sets the framework for the design, implementation, and quality management of the project. Once project quality objectives are defined, a quality management program can be developed. Quality system documentation detailing this quality management program is then created which describes all the activities specifically designed for controlling and evaluating the data in order to satisfy the project objectives.

2.3 QUALITY SYSTEM DOCUMENTATION

The EPA quality policy requires every EICAA to have written and approved quality system documentation (e.g., QAPPs) prior to the start of the EICAA. This policy and the information included in this section applies equally to intramural and extramural quality system documentation. The purpose of the documentation is to specify the policies, organization, objectives, and the quality assurance activities needed to achieve the project objectives of an EICAA. It is the responsibility of the PO to

adhere to this policy. GLNPO employs a checklist that can be used by the PO and the Quality Manager to determine if formal quality system documentation is necessary for a given project (Appendix F). If the PO proceeds without approved quality system documentation, they are fully aware of the risks and assumes all responsibility. This risk should only be taken in extreme emergencies. The PO also bears the responsibility of providing copies of the approved quality system documentation to each individual who has a major responsibility in the EICAA and explaining the elements of the quality system documentation to these individuals.

If a Quality Assurance Project Plan (QAPP) is deemed to be required by the PO and Quality Manager, QAPPs are prepared, reviewed, and approved in accordance with EPA QA/R-5, *EPA Requirements for Quality Assurance Project Plans* (Appendix G). This document identifies and defines the 24 elements that must be addressed in all formal QAPPs. For some EICAAs, only a subset of the 24 elements may be applicable and according to GLNPO's graded approaches, GLNPO only requires that applicable elements are addressed in quality system documentation. These graded approaches are further discussed in Section 2.3.1.

Review of the quality system documentation must include principal investigators, the PO, and the Quality Manager. It is recommended that the document be reviewed by the PO before submission to the Branch Chief and Quality Manager. The Quality Manager will review quality system documentation for the required elements, the soundness of the quality assurance activities, and compliance with GLNPO's quality system. The Quality Manager will provide written comments on each element, which will be accompanied by a QAPP or QMP checksheet (Appendix J). The checksheet is a summary that alerts the PO as to whether or not QA requirements have been adequately described. The Quality Manager will attempt to review quality system documentation within 10 working days of submission.

All quality system documentation should be filed with the GLNPO Document Control Coordinator (DCC), who will identify the document with a unique document control number (see section 5). At present, this will be accomplished manually, however, an automated system is planned. All original copies of the quality system documentation will be secured by the DCC. The Quality Manager will maintain a hard- and soft-copy of the QM review for the quality management files. Tracking of quality system documentation will be accomplished by the GLNPO Quality Manager utilizing "QATRACK" a database system described in Section 2.6.

2.3.1 GLNPO'S GRADED APPROACHES TO QUALITY SYSTEM DOCUMENTATION

All EICAAs conducted by GLNPO staff (including Federal or private employees retained for GLNPO services and located at the GLNPO offices) must be covered by appropriate quality system documentation prior to the start of the EICAA. In the past, GLNPO has used a four-tiered project category approach to its quality management program in order to effectively focus quality management activities. This approach was developed by the U.S. EPA, Risk Reduction Engineering Laboratory, Cincinnati, Ohio (EPA/600/9-89/087). As stated in this year's QAARWP, GLNPO is no longer using these categories for development and review of QAPPs. However, for historical clarification, GLNPO's base monitoring program falls under Category 2 and a QAPP meeting these requirements is being implemented in support of that program. Guidelines for each of these categories can be found in EPA document EPA/600/9-89/087.

Every expenditure that GLNPO makes towards EICAAs, and every intramural project that collects environmental information driven by environmental decisions should have some documentation commensurate with the importance of the question that is being addressed. GLNPO's graded approaches

for quality system documentation for secondary data, modeling, consortium grants, habitat/ecosystem restoration, and sediment assessment are discussed in Section 7.2.1 and examples are included in Appendix K.

2.4 STANDARD OPERATING PROCEDURES

Good laboratory practices and good management of field sampling operations include the development and use of standard operating procedures (SOPs) for all routinely used sampling, preparation and analytical laboratory methods, and the housekeeping that supports them. SOPs facilitate comparability of data generated at different times, or by different field or laboratory staff. These protocols should be detailed enough so that someone else can reproduce results using the SOP (i.e., a journal article is usually not sufficient).

GLNPO will use SOPs to reduce variability in processes that are performed repeatedly by multiple staff. During the planning phase of any EICAA, GLNPO will identify tasks that will be performed routinely or by multiple staff, and will develop procedures for performing these tasks. SOPs are written by the individuals performing the procedure and are reviewed by one or more individuals with appropriate training and experience with the process. The SOPs not only serve to ensure that routine tasks are performed correctly and consistently, but also provide the basis for staff training programs. The GLNPO Quality Manager will review and audit staff conformance to SOPs and make recommendations for updating these procedures annually. The POs in conjunction with the Quality Manager will work with the principal investigators and quality staff from their organization to identify the procedures that would benefit from the use of SOPs. This approach for developing and approving SOPs for use in new and ongoing projects provides GLNPO with the following benefits:

- ▶ consistency in performance, particularly in conducting data review and validation tasks;
- ▶ improved data comparability, credibility, and defensibility;
- ▶ reduced errors; and
- ▶ increased efficiency in performing tasks, thus lowering costs.

In 2000, GLNPO developed a comprehensive manual titled, *Sampling and Analytical Procedures for GLNPO's Water Quality Survey of the Great Lakes*. GLNPO reviews all SOPs in the manual for improvement and clarity during performance of the WQS and will develop new SOPs for appropriate activities. This manual will be updated yearly using appropriate document control procedures to incorporate improvements and clarifications identified during the survey. A controlled copy of this document is maintained by GLNPO to ensure that all individuals participating in the survey have and employ current SOPs (Section 5).

Recommended Elements of an Analytical SOP

- ▶ Scope and Application
- ▶ Method Summary
- ▶ Sample Handling and Preservation
- ▶ Interferences
- ▶ Safety
- ▶ Equipment/Materials/Reagents
- ▶ Calibration
- ▶ Procedure
- ▶ Calculations
- ▶ QA/QC
- ▶ References

The elements listed above are recommended but will not be strictly enforced due to the fact that methods may be used that have been previously documented. However, long-term programs should contain SOPs that include these elements, presented in a form that is useful to anyone performing the method.

Methods can be included in the quality system documentation either in the body of the document or as an appendix. If the referenced method is not followed precisely, addendums to the method must be included in the documentation that clearly identifies changes to the method, such that changes are obvious to any individual using the method. If this altered method is used for an extended period of time, the full method must be revised and submitted. A method *cannot* be revised during project implementation without the prior consent of the PO. If the modification is accepted, it must be documented in a letter to the PO and included in the next submitted report. It is the responsibility of the PO to inform all relevant project participants of the protocol change.

Laboratories working with GLNPO should have a good laboratory practices document that is available for review during technical audits. GLPs refer to the general practices that relate to the majority of measurements such as: facility and equipment maintenance, record keeping, chain-of-custody, reagent control, glassware cleaning, and general safety.

2.5 TRAINING

In order to facilitate staff awareness of the quality system, all GLNPO staff involved in EICAAs will receive a training course on the quality system based on this QMP. As part of the training, staff will be given an overview of the contents of this QMP and the location, electronically and hard-copy, of the current QMP. Staff also will be encouraged to use the QMP as a reference in support of EICAA's. Management personnel receive additional training on their specific roles and responsibilities for implementing GLNPO's quality system. GLNPO's quality management staff receive additional training on quality planning, documentation, and assessment. Section 3 provides detailed information regarding GLNPO's training requirements for quality management.

2.6 TRACKING ENVIRONMENTAL INFORMATION COLLECTION ACTIVITIES

Due to the number of assistance agreements funded each year, GLNPO developed and employs a database system (QATRACK) to track the development, review, and approval of quality system documentation for all EICAA's involving GLNPO funds. The database assists GLNPO with ensuring that all grants and contracts have the required quality system documentation as determined by the Quality Manager and PO. Because quality system documentation must be approved *prior* to initiation of an EICAA, the Quality Manager is part of the assistance agreement signature chain (see Appendices H and I), allowing for the earliest possible tracking of the agreement. Data are entered into QATRACK during the assistance agreement start-up stage, upon review and signature approval of the agreement by the Quality Manager. QATRACK has the capability to capture multiple rounds of submissions and reviews of the quality system documentation.

The QATRACK database also is used to prepare reports on the status of quality system documentation for ongoing EICAAs. GLNPO's Quality Management Team uses the database to assist them in preparing reports to management that provide the number of ongoing EICAAs and the status of required quality system documentation. The database was designed also to function as a management tool for evaluating adherence to the quality system and staff workload distribution. QATRACK is a Microsoft Access-based application with one version available for the Quality Manager for entry, editing and archive, and a second version available to staff which is "write protected" for review and query.

GLNPO is in the process of developing a version of this system in Oracle, GLNPO's Project Tracking Database (PTD) and hopes to implement the system in the last quarter of FY 2002. When implemented, information for new projects will be entered into the PTD and information for past projects will be rolled over into the new database as time allows. The database will be organized according to nine tabs as follows:

Tab 1: General Project Information

- ▶ GLNPO ID # (alpha-numeric)
- ▶ Funding Mechanism (grant, interagency agreement, cooperative agreement, contract, in-house, procurement request)
- ▶ Assistance Agreement #
- ▶ Contract #
- ▶ Solicitation Type (text)
- ▶ DCN # (alpha-numeric)
- ▶ Title of Project (text)
- ▶ Project Summary/Description (text)
- ▶ Project Type (research or demonstration; survey, study, or investigation; other)
- ▶ PI Information (name, address, phone, fax, email, organization name, organizational type [checklist: State; Interstate Agency or Commission; Sub-state or special purpose district; County; Municipality; Federal Agency; College or University; Tribal Organization; Federally funded research and development center; Individual; For-profit Company; or Other])
- ▶ PO Information (name, phone)
- ▶ Category (contaminated sediments, ecological protection and restoration, pollution prevention and reduction, monitoring, indicator development, invasive species, strategic or emerging issues, LaMP, GLWQA, GPRA, other)
- ▶ Lake basin (Ontario, Erie, St. Clair, Huron, Michigan, Superior, Connecting Channels, AOCs [list all out] All, Other)
- ▶ State/province where project is located (NY, PA, OH, MI, IN, IL, WI, MN, Ontario, All, Other)
- ▶ Congressional district (text)
- ▶ Project Location (text)
- ▶ Project period start (date)
- ▶ Project period end (date)
- ▶ Amendment start date(s)
- ▶ Amendment end date(s)
- ▶ Amendments (open)
- ▶ Award date
- ▶ QA needed (yes or no)
- ▶ Peer review needed (yes or no)
- ▶ Data to GLENDAs (yes or no)
- ▶ Keyword (text)
- ▶ Comments (open field)

Tab 2: Grant, Cooperative Agreement, Interagency Agreement Pre-Award Phase

- ▶ GLNPO ID #
- ▶ Funded? (Yes/no)
- ▶ Amount requested (money)
- ▶ Amount match (money)
- ▶ Preproposal (open field to attach document)
- ▶ Technical screening (checkbox)
- ▶ Lake team recommendations (checkbox)
- ▶ Recommendations to management (checkbox)

- Management decision (checkbox)
- Date of Management decision
- Comments (open field)

Tab 3: Grant, Cooperative Agreement, Interagency Agreement Award Phase

- GLNPO ID #
- Grant specialist name and phone
- Budget period start (date)
- Budget period end (date)
- Fiscal year
- Amount obligated (money)
- Amount matched (money)
- Congressional earmark? (Yes/no)
- Date of full proposal request letter
- Date full proposal received
- Date documents/checklist come from assistance section
- Date commitment notice sent (GLNPO)
- Date of decision memo
- Date final documents come from assistance section
- Date assistance agreement to NPM
- Comments (open field)

Tab 4: Grant, Cooperative Agreement, Interagency Agreement Project Management Phase

- GLNPO ID #
- Progress report frequency (open)
- Site visits (date) (be able to enter in multiple dates)
- Site visit report (open field) (be able to enter in multiple reports)
- Program requirements checklist (progress report, draft of final report, final report, project documentation, payment, meetings/conferences, subcontracting, quality assurance, locational information, data reporting, safety manual, signage, disposition of wastes, other)
- Date progress reports due
- Date progress reports received
- Progress reports (open field)
- Date receive QA plan
- Unliquidated obligations (open field)
- Unliquidated obligations dates
- Date of financial status report
- Financial status report (checkbox)
- Comments (open field)
- Reminder e-mail sent (checkbox)
- Recipient contacted (checkbox)
- Demand letter sent (checkbox)
- Delinquency notice sent (checkbox)
- Letter sent to branch chief (checkbox)
- Letter sent to grantee from BC (checkbox)
- Teleconference (checkbox)
- Suspension letter sent from BC (checkbox)
- Meeting to discuss options (checkbox)
- Comments (open)

Tab 5: Grant, Cooperative Agreement, Interagency Agreement Project Closeout Phase

- GLNPO #
- Final document checklist (MBE/WBE, property, inventions, final FSR)
- Money expended
- Final report received (yes/no)
- Final report approved (yes/no)
- Final report (open field)
- Final report location (eg.: web address)
- Date closed-out
- Comments (open field)
- Reminder letter from assistance (check mark)
- Contact recipient prior to due date (check mark)
- Recipient contacted on due date (check mark)
- Demand letter sent (check mark)
- Teleconference (check mark)
- Delinquency notice sent (check mark)
- Letter sent to branch chief (check mark)
- Letter to grantee from director (check mark)
- Teleconference (check mark)
- Suspension letter sent to grantee (check mark)
- Teleconference (check mark)
- Debarment and suspension call and letter sent (check mark)
- Comments (open)

Tab 6: Contracts

- GLNPO ID #
- Statement of work/Specifications (open field)
- Contract specialist name and phone
- Contract officer name and phone
- Contracting Officers Representative Training (yes or no)
- Contracting Officers Representative Training Form (open)
- Work assignment/Task order (open)
- Work assignment # / Task order #
- Work assignment/Task order Start Date
- Work assignment/Task order End Date
- Work plan (open)
- Technical Directive (text)
- Technical Directive (date)
- Procurement Request (open)
- Date of procurement requisition
- Procurement requisition amount (\$)
- Committed amount (\$)
- Amount (\$)
- Date of commitment
- DCN # (text)
- Comments (open)

Tab 7: Communications

- GLNPO ID #
- Final report submitted to GLNPO? (yes/no)
- Web information (open)
- Press release (open)
- Fact sheet (open)
- Journal article publication (open)
- Outreach/Tech transfer planned (open)
- Slides (open)
- Comments (open)

Tab 8: Quality System Documentation

- GLNPO ID #
- Date entered
- Quality system documentation (check QMP or QAPP)
- Quality system documentation (open)
- Quality system documentation type (modeling, habitat restoration, secondary data, monitoring, research analytical, sediment assessment, sediment remediation)
- Date QS documentation due
- GLNPO Lead
- Funding branch
- Funding team
- Date to QA manager
- Quality system review checksheet (open)
- Initial approval date
- QA approval ID
- Approval status (no submittal, under review, approved, approved w/minor revisions, unacceptable, delinquent)
- Date of review completion
- Date of final approval
- Audit checksheet (open field)
- Date of audit
- Audit summary report (open field)
- Data files (open field)
- Data assessment report (open field)
- Comments (open field)
- Contacted recipient (check mark)
- Second contact with recipient (check mark)
- Delinquent but not significantly affecting quality (check mark)
- 1st Phase Delinquency (check mark)
- Letter sent to PO (check mark)
- Teleconference (check mark)
- Cc letter sent to branch chief (check mark)
- 2nd Phase Delinquency (check mark)
- Letter sent to branch chief (check mark)
- Seriously Delinquent (check mark)
- Letter sent to grantee from director (check mark) Suspension letter sent to grantee (check mark)

- Teleconference (check mark)
- Debarment and suspension call and letter sent to grantee (check mark)
- Withdraw funds (check mark)
- Comments (open)

Tab 9: Peer Review

- GLNPO ID #
- Date entered into peer review database
- Objective (open)
- Cross-cutting science issues (older Americans, children's health, tribal science, contaminated sediments, cumulative risk, indoor environments, environmental justice, genomics)
- Peer Review Leader (name and phone)
- Science Category (major scientific/technical, non-major scientific/technical, major economic, non-major economic, major social science, non-major social science, other)
- Environmental Regulatory Model (new, modified, new application, N/A)
- Environmental Medium (air, human health, multimedia, terrestrial, water, other)
- Peer Review Type (internal, external, to be determined)
- Peer Review Mechanism (text)
- Results of Peer Review Comments (substantive revision to final product, minor revision to final product, no significant change to final product, product was terminated, to be determined)
- Peer Review Charge/Instructions (open)
- Peer Reviewer Name & Affiliation (text)
- Peer Review Comments (open)
- Management Decision on Comments (open)
- Location of Peer Review File (text)
- File Contact Name, organization, telephone (text)
- Additional Supporting Documentation / Comments (open)
- Date of projected peer review
- Date peer review was conducted
- Date peer review was completed
- Date final peer review comments were received
- Date of management decision on peer review comments
- Comments (open)

2.7 QUALITY MANAGEMENT TEAM MONTHLY REPORTS TO MANAGEMENT

GLNPO's Quality Management Team presents a status report on quality management activities associated with all GLNPO-funded EICAA's each month during a management meeting. GLNPO uses a monthly quality assurance status tracking sheet (Appendix C) to summarize and present the status of these activities to management. The Team provides for all outstanding EICAA's, a list of required quality system documentation, the due dates for the documentation, and the review and approval status of the documentation. These reports are designed to also serve as a management tool to evaluate office work loads.

2.8 REVIEWS OF QUALITY SYSTEM IMPLEMENTATION AT THE BRANCH LEVEL

GLNPO recently established a new procedure to facilitate assessing quality system implementation at the Branch level. GLNPO's Office Director will meet with each Branch Chief twice yearly regarding adherence to the quality system by all EICAA's administered through the branch. Prior to the meeting, GLNPO's Quality Manager will prepare a briefing document on implementation of the

quality system, including the status of quality system documentation, the status and results of all technical system audits or reviews, and outstanding issues. This meeting will function to close the loop on the quality system cycle from planning and implementation to assessment and applying corrective action when needed.

2.9 ANNUAL REPORT AND WORKPLAN

GLNPO is required to submit a quality assurance annual report and workplan (QAARWP) to OEI's Quality Staff. GLNPO's Quality Manager will follow the outline provided by Quality Staff. Every year, GLNPO's Quality Management Team prepares a performance agreement along with the other GLNPO functional teams. This performance agreement serves as the workplan within the annual report. In the annual report, an inventory of all EICAA's is provided that includes: information regarding the number of quality system documentation packages that were submitted to GLNPO and reviewed throughout the year, the status of quality system documentation for all ongoing and scheduled EICAAs, and an overview of workload distribution within the office. The report is organized so that it can be used as management tool for assessment of EICAA's and staffing issues.

2.10 QUALITY SYSTEM AUDITS AND TECHNICAL SYSTEM AUDITS

Quality systems audits (QSAs), previously termed management systems reviews, are on-site evaluations by internal or external parties to determine if the organization is implementing a satisfactory quality management program. They are used to determine the adherence to the program, the effectiveness of the program, and the adequacy of allocated resources and personnel to achieve and ensure quality in all activities. Internal QSAs are conducted by GLNPO senior management. GLNPO-funded entities also may undergo QSAs lead by GLNPO's Quality Manager. External QSAs are conducted by EPA Quality Staff to determine compliance of GLNPO's program with this QMP. Technical systems audits (TSAs) are qualitative on-site evaluations of all phases of an EICAA (i.e., sampling, preparation, analysis). These audits can be performed prior to or during the data collection activity, in order to evaluate the adequacy of equipment, facilities, supplies, personnel, and procedures that have been documented in the quality system documentation. Because a TSA is most beneficial at the beginning of a project, GLNPO schedules audits at the initiation phase of an EICAA, when possible. GLNPO performs a QSA, site visit, or TSA for the most high-profile EICAA's (i.e., those that support an important decision). The number and frequency are dependent on the length of the project, the importance of the project objectives, and the evaluations of prior audits. Technical System Audits and QSAs are discussed in Section 9.1

Section 3

Personnel Training and Qualifications

The success of any quality management program ultimately lies with the personnel who implement the program on a daily basis. GLNPO must not only support activities that will satisfy the mandatory quality management program, but also instill the philosophy of improving activities to provide the highest quality data in a cost-efficient manner. It is GLNPO policy to provide the quality system training necessary to ensure that all staff involved with the generation and use of environmental data understand and use GLNPO's quality system. Management is committed to ensuring that GLNPO personnel responsible for EICAAs have the necessary education, training, and experience to develop, control and evaluate data quality. The following sections describe GLNPO's quality system training program.

3.1 QUALITY MANAGER TRAINING

The Quality Manager regularly attends national and, in some cases, international conferences and meetings on quality systems and the development of quality management materials and protocols relevant to GLNPO. The Quality Manager will participate in training courses on quality management topics, such as data quality assessment and QAPP development. This will assure that GLNPO personnel receive up-to-date training on a variety of quality assurance subjects including EPA's quality policy.

3.2 GLNPO PERSONNEL QUALITY SYSTEM TRAINING

Supervisors are responsible for ensuring that staff have the qualifications to do their jobs, including those related to the quality system. Managers are responsible for discussing quality training needs with personnel involved in EICAAs during the mid-year and annual personnel performance evaluations.

In addition, because line management is ultimately responsible for the quality of data, managers and supervisors also must receive the necessary training to ensure their understanding of the importance of the quality system, their responsibilities as managers of data collection activities, and specific GLNPO quality system policies and procedures.

Repetition is critical to raising awareness

Training schedules will be developed in order to optimize attendance. Training may consist of seminars or classes, or on-the-job training. If training cannot be met through in-house expertise, it may be accomplished through external organizations. Training also will be available to all personnel cooperating on GLNPO projects (universities, other agencies etc.). It will be the responsibility of the GLNPO projects leads to make cooperators aware of these training opportunities. The Quality Manager will provide the following training at least every three years:

- ▶ Overview of GLNPO's Quality System
- ▶ QA Project Plan development
- ▶ GLNPO Quality System Training for Project Officers
- ▶ Auditing and data verification/validation techniques

The Quality Manager will develop a library of pertinent quality management documentation to assist GLNPO technical staff. The library will include documentation as well as software training programs. The minimum required quality management training for GLNPO staff is detailed in Table 3-1.

Table 3-1. Quality Management Training Requirements for GLNPO Staff

Position	Quality Management Training Requirements
Managers (Branch Chiefs, Division Directors)	<ul style="list-style-type: none"> ▶ Overview of GLNPO's Quality System (every 3 years) ▶ Orientation to Quality Assurance for Managers (1 time only)
Work Assignment Managers, Project Managers, Project Officers	<ul style="list-style-type: none"> ▶ Overview of GLNPO's Quality System (every 3 years) ▶ GLNPO Quality System Training for Project Officers (every 3 years)
GLNPO Quality Management Team	<ul style="list-style-type: none"> ▶ Overview of GLNPO's quality system (every 3 years) ▶ Development of Quality Assurance Project Plans (1 time only) ▶ Data Quality Assessment (1 time only) ▶ Development of Quality Management Plans (suggested course)
All GLNPO staff involved in the generation or use of environmental information	<ul style="list-style-type: none"> ▶ Overview of GLNPO's quality system (every 3 years)

Attendance at the courses will be recorded, and attendees will receive a written record from the Quality Manager or instructor after completion of a course. The Quality Management Team will maintain records of the quality system training taken by personnel in each Program Office. A summary of the quality system training will be provided in the annual report, including, but not limited to, a list of the courses offered, the number of attendees, and a listing of all participating organizations. Whenever a new QMP is developed or whenever significant revisions to the QMP are conducted, training will take place within 6 months of approval of the QMP by OEI's Quality Staff in order to ensure GLNPO staff are fully informed of the quality system at any given time.

Section 4

Procurement of Items and Services

GLNPO must ensure that procured items and services meet EPA regulations, are delivered in a timely fashion, and are within GLNPO's specifications. The following sections describe GLNPO's procurement procedures.

It is GLNPO policy that quality system requirements be explicitly addressed when acquiring items or services that involve EICAA's. This policy applies to procurements such as contracts, as well as to cooperative agreements, partnership agreements, grants to institutions of higher education, and other non-profit organizations, Tribes, States, local governments, and interagency agreements. The following Federal regulations contain sections relating to quality management or quality systems:

- ▶ 48 CFR Part 46. Quality Assurance
- ▶ 40 CFR Part 30. Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations
- ▶ 40 CFR Part 31. Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments
- ▶ 40 CFR Part 35. State and Local Assistance

In addition, there are other rules and regulations that apply to contracts and other forms of financial assistance, including grants, assistance agreements, performance partnership agreements, and interagency agreements, as described below.

4.1 PROCUREMENT OF ITEMS

GLNPO utilizes the services of the EPA Region 5 Purchasing Section of the Contracts and Grants Branch for its procurement needs. The Purchasing Section follows the guidelines in Section 13 of the Federal Acquisition Regulations (FAR) which establishes government-wide policies and procedures governing the acquisition process. Two EPA documents: EPA 1900-Contract Management Manual and the EPA Acquisition Regulation Manual (EPAAR) have been developed to supplement the FAR. Region 5 is required to implement the regulations in these documents. EPA attempts to purchase through FAR mandatory sources (i.e., GSA): items on the FAR source list that meet the minimum specifications on the procurement request must be purchased through a FAR source. Procurements of computer hardware and software have a distinct process. Computer procurements will be developed by the Information Management and Data Integration Team and adhere to Region 5 policy.

Requests for purchases and identification of funds begins at the planning stages of any GLNPO project. In order to assure agreement among GLNPO POs, principal investigators, and the Region 5 Purchasing Section, requesters should explicitly identify all items and associated specifications required to meet the government's minimum needs. These specifications will be required during the procurement process. In order to provide the Region 5 Purchasing Section with the correct information, it is suggested that the specifications be developed or reviewed with a purchasing agent before initiating the procurement request. This will assure that the GLNPO requestor will receive the proper item and reduce the chances of purchase delays or incorrect purchases due to inadequate product specifications. The purchasing agent also can assist the requestor in preparing the procurement request form.

GLNPO utilizes procurement request forms (EPA form 1990-8) to initiate requests. These forms will be reviewed by the GLNPO planning and management staff for completeness and accuracy then

forwarded to appropriate GLNPO staff for required GLNPO reviews and approvals. The procurement request will then be forwarded for additional reviews and approvals to the Region 5 Budget Office. The Budget Office certifies that funds are available and the Budget Services Center assigns a document control number (DCN). The Budget Office forwards the procurement request to the Property Management Officer for signature. Finally, the request is sent to the Region 5 Purchasing Section. The approval process may take up to two weeks from the time the procurement request is written until it arrives at Region 5 Purchasing for approval and procurement. If the item is required sooner, the procurement request must be "walked through" the approval process.

4.2 PROCUREMENT OF SERVICES

Two types of mechanisms are principally used to procure services; contracts and assistance agreements (grants, interagency agreements etc.). At GLNPO, contract officers are the only individuals authorized to obligate funds for services.

Certain activities are of a policy and decision-making nature and should remain the sole authority of the EPA. Therefore, contracts or assistance grants should not include the following services:

- ▶ the actual preparation of Congressional testimony;
- ▶ the interviewing or hiring of individuals for employment by EPA;
- ▶ developing and/or writing of Position Descriptions and Performance Standards;
- ▶ the actual determination of Agency policy;
- ▶ participating as a voting member on a Performance Evaluation Board; participating in and attending Award Fee meetings;
- ▶ preparing Award Fee letters, even under typing services contracts;
- ▶ the preparation of documents on EPA letterhead other than routine administrative correspondence;
- ▶ reviewing vouchers and invoices for the purposes of determining whether cost hours, and work performed are reasonable;
- ▶ the development of Statements of Work, Work Assignments, Technical Direction Documents, Delivery Orders, or any other work issuance document under a contract the contractor is performing or may perform;
- ▶ on behalf of EPA, actually preparing responses to audit reports from the Inspector General, General Accounting Office, or other auditing entities;
- ▶ on behalf of the EPA, actually preparing responses to Congressional correspondence;
- ▶ the actual preparation of responses to Freedom of Information Act requests, other than routine, non-judgmental correspondence--in all cases, EPA must sign it;
- ▶ any contract which authorizes a contractor to represent itself as EPA to outside parties; and
- ▶ conducting administrative hearings.

In the past, contract and assistance agreements were utilized to provide QA/QC support to EICAAs. Such use of non-EPA personnel could result in situations in which inherent government functions are being performed by non-governmental personnel or in which potential conflict of interest could occur. Table 4-2 lists quality management tasks as either EPA only tasks or discretionary tasks which may be performed by EPA or non-EPA support staff.

Table 4-2. Quality Management Task Performance by EPA and Non-EPA Personnel

Quality Management Task	Details	Performed by:
Manage and coordinate quality system (quality management program)	<ul style="list-style-type: none"> ▶ Manages the day-to-day operation of GLNPO's mandatory quality system (quality management program) ▶ Acts as a liaison between the organization and OEI's Quality Staff on matters of quality policy ▶ Coordinates with senior management on the development and preparation of the organization's QMP that describes the quality system implemented by the organization ▶ Coordinates with senior management on changes to the quality system as needed to assure its continued effectiveness and reports the results annually to management and to OEI's Quality Staff in the QA Annual Report and Workplan (QAARWP) ▶ Manages organization resources designated for the quality system (quality management program) ▶ Maintains pertinent records of all quality system activities performed by the organization 	EPA only
Review and approve procurement and financial assistance documents for QA requirements	<ul style="list-style-type: none"> ▶ Reviews procurement and financial assistance documents to confirm that any need for QA requirements has been established, provides any necessary special language or conditions for such QA requirements, and approves by signing the appropriate Quality Assurance Review (QAR) Form ▶ Participates directly or indirectly in the proposal or cooperative agreement/grant review processes to advise the PO on the suitability of the offeror's Quality System (QA program) or QA/QC approach for the particular project. ▶ Reviews work assignments to certify that appropriate QA requirements have been established and that the necessary instructions are being communicated to the contractor to carry out the expected QA/QC tasks and provides signature approval 	EPA only
Review and approval of quality management planning documents	<ul style="list-style-type: none"> ▶ Reviews QA Project Plans (QAPPs) for all projects, work assignments, grants, cooperative agreements, and inter-agency agreements involving data acquisition, data generation, and/or measurement activities that are performed on behalf of EPA 	EPA only
	<ul style="list-style-type: none"> ▶ Approves all QAPPs for implementation in all applicable projects, work assignments, grants, cooperative agreements, and inter-agency agreements performed on behalf of EPA and where specific approval of QAPPs has been delegated to a responsible EPA official, the Quality Manager reviews the QAPPs for concurrence 	

Quality Management Task	Details	Performed by:
	<ul style="list-style-type: none"> ▸ Coordinates the correction of deficient QAPPs with the PO and his/her management, and assures through appropriate procedures (e.g., contract, financial assistance) that no data collection operations commence before a QAPP is approved 	
	<ul style="list-style-type: none"> ▸ Reviews, at the specific technical direction of the Quality Manager, QAPPs and other QA-related planning documents, such as sampling and analysis plans, DQO specifications, etc., to determine if the proposed QA approach documented is adequate for the work planned, based on explicit evaluation criteria provided by the Quality Manager (the reviews should identify specific technical deficiencies in the QAPP to the attention of the Quality Manager) 	Discretionary tasks
Review and technical assistance in developing and preparing experimental designs	<ul style="list-style-type: none"> ▸ Interprets Agency policy and requirements pertaining to developing and preparing experimental design requirements ▸ Provides corrective action technical assistance and guidance to intramural and extramural researchers to enable them to produce, in a timely manner, satisfactory experimental design documents using the DQO process 	EPA only
	<ul style="list-style-type: none"> ▸ Using explicit criteria provided by the Quality Manager, reviews experimental designs produced to determine if satisfactory results can be obtained from the design and provides the Quality Manager with a technical assessment of strengths and weaknesses in the design 	Discretionary tasks
Tracking and reporting of QA program deliverables	<ul style="list-style-type: none"> ▸ Tracks critical QA program deliverables for the organization and makes periodic reports to senior management on the status of reporting actions and deliverables 	EPA only
	<ul style="list-style-type: none"> ▸ Compiles/logs administrative management information including: <ul style="list-style-type: none"> - turnaround times to correct QAPPs, - responses to audits, and - quality reviews of final reports 	Discretionary tasks
Management of contractor support work assignments	<ul style="list-style-type: none"> ▸ Serves as PO of record for contracts established to provide QA support to the organization and usually serves as the Work assignment manager (WAM) for specific work assignments involving QA activities within the same or other contracts 	EPA only
Conduct management assessments	<ul style="list-style-type: none"> ▸ Plans, directs/conducts, and reports to senior management the results of annual assessments of effectiveness of the quality system (QA program) being applied to EICAA's. ▸ Coordinates with senior management any revision of the quality system (QA program) as necessary based on findings of the assessment. 	EPA only

Quality Management Task	Details	Performed by:
	<ul style="list-style-type: none"> Provides technical support to EPA Quality Manager in the planning phase of management assessments (such activities are limited to the assembly and compilation of background information and data, guidance documents, technical reports, etc., available in public domain, for use by EPA in designing the assessment goals and specifications) 	Discretionary tasks
Conduct technical assessments	<ul style="list-style-type: none"> Plans and directs, with the responsible EPA PO, the implementation of periodic technical assessments of ongoing EICAAs that technical and quality objectives are being met and that needs of the customer are being satisfied (such assessments include technical systems audits, audits of data quality, surveillance, performance evaluations, and data quality assessments) 	EPA only
	<ul style="list-style-type: none"> Performs technical assessment (as listed above) of the organization's EICAAs, both intramural or extramural according to a specific plan prepared by the Quality Manager in the presence of the Quality Manager or authorized EPA official (preparations for such assessments may include the acquisition or development of audit materials and standards. Results (findings) are summarized and presented to the Quality Manager, or authorized EPA official, for determination of conclusions and necessary actions, if any) 	Discretionary tasks
Preparation and presentation of quality management subjects in the technical literature and at meetings/symposia	<ul style="list-style-type: none"> Represents EPA in transferring quality management subjects to other Agency, public, or scientific groups through: <ul style="list-style-type: none"> - participation in technical meetings and symposia, and - participation in technical literature, including peer-reviewed journal papers, oral presentations, and panel discussions 	EPA only
	<ul style="list-style-type: none"> Transfers quality management subjects to other groups through participation in technical meetings and symposia and through the technical literature, with appropriate disclaimer that the information does not represent EPA policy or position (only EPA personnel may represent the Agency in an official role) 	Discretionary tasks
Research relative to quality management issues	<ul style="list-style-type: none"> The Quality Manager should be kept abreast of advances in quality management through technical literature, training, and symposia to create opportunities for improvements to the organization's quality system (QA program) Performs searches of the technical and quality management literature relative to specific QA/QC issues including compiling summaries of alternative sampling and analytical methods, identification of QC reference material, and availability of standard operating procedures for calibrating certain instrumentation 	Discretionary tasks
Preparation and presentations of QA training materials and courses	<ul style="list-style-type: none"> Develops and presents detailed guidance and training for QA/QC activities based on interpretation of Agency-wide requirements and guidance. 	EPA only

Quality Management Task	Details	Performed by:
	<ul style="list-style-type: none"> Provides or coordinates quality-related training for the organization in special skill areas not generally available to the organization Provides assistance in preparing and presenting quality-related technical training (within constraints of potential conflict of interest) 	Discretionary Tasks
Quality review and approval of final reports	<ul style="list-style-type: none"> Defines criteria for the acceptability of quality documentation in the organization's published papers and reports Approves for publication only those papers and reports that contain an adequate discussion of the quality of the projects results and the usability of the data produced 	EPA only
	<ul style="list-style-type: none"> Conducts a review of all reports produced by the organization using the qualitative and quantitative specifications obtained from the DQO process to ensure that an adequate discussion of the quality of the project results and the usability of the data produced are included (This quality review complements the peer review process and documents that the results of the EICAA have or have not been reconciled with the quality objectives. Results of any reviews performed by non-EPA support personnel are presented to the Quality Manager for decision on the acceptability of the report) 	Discretionary tasks

As it does for procurement of items, GLNPO utilizes the services of the EPA Region 5 Contracts Management Branch for the procurement of services. This group must approve all contracts and agreements before they are implemented. It is GLNPO policy that before any funding of contracts or agreements containing EICAAs is initiated, appropriate quality system documentation must be submitted. To that end, all procurement packages and associated quality system documentation are reviewed by the Quality Manager. The documentation must be reviewed by the GLNPO Quality Manager and determined to be "acceptable with minor revisions" (see Appendix J) prior to initiation of an EICAA. Information on the development of quality system documentation is detailed in Section 2. In order to determine whether quality system documentation is required, GLNPO POs can use the Quality System Documentation Checklist (Appendix F). The PO is responsible for ensuring that the technical requirements of the quality system are satisfied. It is GLNPO policy that all POs overseeing contracts and assistance agreements be certified through PO and contract administration training.

4.2.1 CONTRACTS

GLNPO conducts procurement functions in accordance with the Federal Acquisition Regulations (FAR), and generally accepted business practices for the acquisition process. The FAR was recently amended to address contract quality systems requirements on a government-wide basis. The new FAR contract clause at 52.246-11, *Higher-Level Contract Quality Requirements* (February 1999), as prescribed by FAR 46.311, allows a Federal agency to select a voluntary consensus standard as the basis for its quality requirements for contracts, and identifies ANSI/ASQC E4-1994, *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs*, as an acceptable standard.

Due to these FAR changes, EPAAR 1546.2, Contract Quality Requirements (March 1984), which is a quality regulation that applies only to EPA, was determined to be unnecessary and the pertinent requirements from EPAAR 1546.2 will be included in the EPA Directive 1900, Contracts Management Manual (CMM).

The EPA Office of Acquisitions Management issued Procurement Policy Notice No. 01-02 in March 2001 that provides guidance for the use of these higher-level contract quality requirements. Notice 01-02 includes two attachments that provide directions for contracting officers and their representatives in the program offices (e.g., PO and Work Assignment Managers), as well as quality staff, and describes the process for determining the quality system requirements that must be included in contract acquisition packages.

Contracts are used when the government derives sole benefit from a particular product or service. Contracts can be specific and require a degree of lead time for development. Depending upon the scope of the service, quality assurance requirements that must be adhered to under the terms and agreements of the contract are developed. Currently, POs and their supervisors are responsible for review of procurement packages. GLNPO relies on the contract officer, PO, work assignment manager, and specialist (as appropriate) to include required documentation. GLNPO quality staff also will assist in the contracting process by evaluating quality system documentation submitted by contractors in response to either pre-award or post-award requirements. As noted in the EPA 1900 -- Contracts Management Manual, a member of the GLNPO's Quality Management Team at the appropriate level will be involved for procurements over \$500,000, in cases where quality system requirements are applicable to the procurement. GLNPO's Quality Manager will generally fulfill this role.

GLNPO's management staff and Quality Management Team play active roles in assisting the contract management staff in defining the quality system requirements for contracts. Contracts involving EICAAs will include requirements for the provision of a quality management plan and quality assurance project plans, or other appropriate quality system documentation.

In procuring services, responsibility does not follow the line of authority. The PO, as a functional person, submits a request stating the desired service, measures the quality of the service, and accepts the service. The Contracting Officer provides the means of getting a contract and enforcing the provision. The PO has overall responsibility to see that the service is provided but works through the contracting officer's authority. The PO is appointed by the Contracting Officer and formally designated as a technical representative of the Contracting Officer in the contract. Project Officers must complete PO and contract administration training to serve on a contract. Chapter 7 of the EPA Contracts Manual (EPA-1900) specifies the required training, experience, and workload limitations for an individual to serve as a PO. GLNPO will adhere to these specifications. Two major tools to ensure that adequate service is provided are a well-defined statement of work (SOW) and quality system documentation that includes reviews (audits).

Whenever the government enters into a contract, it is entitled to receive quality service. In order to define and measure quality, the PO must develop a statement or scope of work (SOW) that will accurately define the minimum acceptable requirements for the service. This is the first step in the procurement process that helps to ensure that services produce results or products of acceptable quality. The PO must succinctly state their expectations of the product or service and be able to relate this to the supplier. Good communication between the PO and the supplier of a product or service is essential to a mutual understanding of what the expectations are and how quality will be defined. Methods used to determine quality (audits, quarterly interviews, random inspections etc.) should be explained prior to project implementation so that the supplier will understand how quality will be assessed. Supplement #2 to OMB circular A-76, A Guide For Writing and Administering Performance Statements of Work for

Service Contracts, provides good guidance for writing SOWs and implementing QA surveillance plans. Another important source of information is the EPA 1900-Contracts Management Manual which specifies all required documents for developing contracts. The Quality Manager will maintain copies of both documents in the QA library.

GLNPO personnel must be aware of "personal services," which are characterized by an employer-employee relationship between government and contractor employees. These contracts are illegal in EPA. Personnel services conflicts arise when government employees assume the right to instruct, supervise, or control a contractor's employee in how they perform work. It is the contractor's right to hire and terminate, to assign, and to organize and implement tasks, as the contracting organization deems appropriate. GLNPO may tell the contractor what to do within the terms and agreements of the contract, but not how to do it.

4.2.2 ASSISTANCE AGREEMENTS

Assistance agreements are used when both parties (EPA and the group providing the service) derive benefit out of the service. This usually occurs with grants, cooperative agreements, or interagency agreements (IAGs) where universities or States derive benefits from participating in EICAAs. If the project involves environmentally-related measurements or generation of either primary or secondary data, then the applicant/recipient must develop and implement a quality management system. Grants are assistance agreements where EPA has no substantial involvement in the project. Cooperative agreements are assistance agreements where EPA has substantial involvement in the project.

As discussed in the EPA proposed Order, *Policy for Competition in Assistance Agreements*, July 15 2002, it is EPA policy to promote competition in the award of assistance agreements to the maximum extent practicable. When assistance agreements are awarded competitively, it is EPA policy that the competitive process be fair and open and that no applicant receive an unfair competitive advantage. It is GLNPO policy to promote fair and open competition in the award of assistance agreements and GLNPO is committed to meeting the specifications of EPA's final order on this subject. This policy will be discussed as part of the staff training session, *Overview of GLNPO's Quality System*.

GLNPO follows guidelines developed in the EPA Assistance Administration Manual (EPA-5700) and in the 4th edition of Managing Your Financial Assistance Agreement - Project Officer Responsibilities (EPA 202-B-96-002, January 2000). Project Officers are responsible for incorporating project materials into the official working files located in the GLNPO central standardized filing system (see section 5).

A Project Inventory and Approval Form (Appendices H and I) is used to determine if a grant or IAG package contains all required components in appropriate format with sufficient documentation. This is usually completed by the PO and the Grants Specialist. The GLNPO Quality Manager also will review the application to determine the QA and peer review requirements and sign this checklist. All decisions on the checklist are sanctioned by the GLNPO Director through signature. The PO is responsible for submitting the checklist to the Quality Manager. The Quality Manager also will use the information for tracking progress on the development of project quality system documentation.

For assistance agreements, SOWs are usually developed jointly. However, once the SOW is completed, the parties also must agree on the quality standards for assuring the product or service. It is the responsibility of the PO to be aware of EPA QA policy and to work with the GLNPO Quality Manager to represent these standards during the development of the projects SOW.

All assistance agreements originating within GLNPO must meet established administrative and quality assurance requirements in the latest editions of the following:

- ▶ Assistance Administration Manual, EPA Directive 5700, 1984 Edition (or later);
- ▶ EPA Order 5700.1, Policy for Distinguishing Between Assistance and Acquisition, March 22, 1994;
- ▶ EPA Order 5730.1, Policy and Procedures for Funding Assistance Agreements, January 21, 1994;
- ▶ 40 CFR Part 30, Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations;
- ▶ 40 CFR Part 31, Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments; and
- ▶ 40 CFR Part 35, State and Local Assistance.

As stated in *Managing Your Financial Assistance Agreement* (EPA 202-B-94-001, May 1994), it is Agency policy that applicants are required to develop and implement quality management practices for all projects involving environmentally-related measurements or data generation. These practices consist of policies, procedures, specifications, standards, and documentation which will produce data of sufficient quality to meet project objectives and will minimize loss of data due to out-of-control conditions or malfunctions. All applicants for grants or cooperative agreements involving environmental programs shall submit quality system documentation which describes the quality system implemented by the applicant, which may be in the form of a quality management plan or equivalent documentation. In keeping with the graded approach described throughout this plan, GLNPO policy requires that all parties receiving EPA grants/financial assistance under which EICAA's are performed include either a quality assurance project plan that has been prepared in accordance with *EPA Requirements for Quality Assurance Project Plans* (Final, March 2001), or equivalent quality system documentation.

The applicant's quality system documentation shall indicate whether the assistance involves an environmental information collection or use. The applicant is requested to submit a description of the its program or project as part of the workplan submitted with Standard Form 424.

The level of documentation must be established by GLNPO staff when planning for the grant or financial assistance. If the applicant has an EPA-approved QMP or QAPP and it covers the project in the application, then they need only reference the plan in their application. The quality assurance project plan must be acceptable to the Award Official in order to receive a grant award.

The grant applicant is responsible for preparing the quality system documentation, which is then reviewed and certified by the Quality Manager or his designee prior to initiation of the EICAA. For financial assistance grants under the purview of Regions, the Regional Quality Assurance Officer or his designee is responsible for the review and approval of the quality system documentation. At the request of the Regional Quality Assurance Officer, the quality system documentation also may be reviewed and cosigned by GLNPO's Quality Manager.

If an applicant is unfamiliar with EPA and the GLNPO quality requirements, the PO should direct them to the appropriate quality staff, either in the GLNPO, or in the Office of Environmental Information. The following are quality requirements by applicant type:

- ▶ If an application is for research financial assistance, the application must include a quality statement which either addresses certain areas or provides justification why specific areas do not apply [see 40 CFR 30.503(d)].

- ▶ If an application is from a State or Tribal government (except for a wastewater treatment construction grant) the applicant must define their plans for completion of the necessary quality system documentation
- ▶ All other applicants must submit quality system documentation with their application.

The decision on whether a grant or cooperative agreement involves environmental information collection or use is determined by the GLNPO PO in consultation with the Quality Management Team and a review of the project workplan. Project Officers approve projects, subject to their terms and conditions, during the “award phase” of the project. At that time, they review award documentation prepared by the Assistance Section, develop and initial a transmittal letter, and pass the package “up-the-chain” for sign off by Team Leaders, Management, and the Great Lakes National Program Manager.

The applicant’s quality system documentation will be reviewed and approved as a condition for award of any assistance agreement. The quality system documentation must be submitted as part of the application (unless GLNPO-approved quality system documentation is cited in the application). If the quality system documentation is not submitted as part of the application, GLNPO will, in some cases, fund the project and include a term and condition in the assistance agreement. This term and condition requires the recipient to submit the quality system documentation within a specified time after award of the agreement and notifies the recipient that they may not begin the EICAA until the GLNPO PO informs them that the quality system documentation has been approved (Section 4.2.3).

When States receiving funds from GLNPO agree to enter into performance partnership agreements with GLNPO, the performance partnership agreements will be used as a mechanism to define the quality system requirements for the effort and to establish the respective roles of and responsibilities of the State and GLNPO in quality management activities.

Interagency agreements that are funded by GLNPO should include quality system documentation requirements in the agreement. Because GLNPO cannot unilaterally impose such requirements, these requirements must be negotiated into each agreement. Policies and administrative procedures governing interagency agreements are defined in Chapter 5 of *Managing Your Financial Assistance Agreement*. The GLNPO quality system requirements related to environmental data apply to all activities funded by GLNPO through interagency agreements. Cooperative agreements that will involve EICAA’s must adhere to the quality system documentation requirements in 40 CFR 30.503. These standards must be included explicitly in all cooperative funding agreements.

All interagency agreements with EICAA’s which GLNPO funds, or participates in, will include quality system documentation. Where GLNPO is providing funds to another organization, that organization is responsible for preparing the quality system documentation. If the other organization has equivalent requirements for quality system documentation, that guidance may be employed. If there are not comparable quality system procedures, the quality system procedures agreeable to both parties must be negotiated prior to initiation of the program or effort and are attached to the Memorandum of Decision. The quality system documentation will be reviewed and certified by GLNPO’s Quality Manager prior to initiation of the EICAA. All proposed cooperative funding agreements shall be reviewed to determine the applicability of quality system requirements as defined in EPA Order 5360.1 A2. This determination shall be documented by the GLNPO Quality Management Team.

Where a quality management plan is required, the plan shall be prepared in accordance with the specifications provided in the most current version of *EPA Requirements for Quality Management Plans* (QA/R-2), which describes the quality system implemented by the party involved in the environmental program. The plan shall define the approving officials of the plan, which, at a minimum will include the GLNPO Quality Manager.

4.2.3 SPECIAL CONDITIONS

Special conditions are usually included in assistance agreements. The PO will list the conditions for which project participants must adhere. One of these conditions relates to quality system documentation. Any assistance agreement that includes environmental information collection activities must include the following statement:

Projects involving collection of environmental data (measurements or information that describe environmental processes, location, or conditions; ecological or health effects and consequences; or the performance of environmental technology) must meet the American National Standard Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs, ANSI/ASQC E4-1994. "Quality System Documentation" includes a Quality Management Plan (QMP), a Quality Assurance Project Plan (QAPP), or such other documentation which demonstrates compliance with ANSI/ASQC E4-1994.

An applicant with current, approved Quality System Documentation will, by the earlier of (i) the 30th day prior to collection of environmental data and (ii) the 90th day after the project start date, notify GLNPO's Quality Assurance Manager of the way it is applying the above standard to this project. In all other cases, Quality System Documentation shall be submitted for approval to GLNPO by the earlier of (i) the 30th day prior to collection of environmental data and (ii) the 90th day after the project start date. Costs associated with data collection are not allowable costs until Quality System Documentation is approved by the GLNPO Quality Manager.

Contact GLNPO's Quality Manager, Louis Blume (312) 353-2317 with questions or to request sample documentation. Further guidance is available in the Grants Requirements/Instruction in the Application Kit and from < http://www.epa.gov/quality/qa_docs.html >, which includes the document "QA/R-5: EPA Requirements for Quality Assurance Project Plans."

In some cases, exceptions to this condition are made. For example, the time constraint may be lengthened in cases where GLNPO is working with State agencies and the funds are going to a subcontract.

Section 5

Document Control and Records

Organizations that perform EICAAs must establish and maintain procedures for the timely preparation, review, approval, issuance, use, control, revision and maintenance of documents and records. A document is any volume that contains information which describes, defines, specifies, reports, certifies, or provides data or results pertaining to environmental programs. As defined in the Records Disposal Act of 1943 (now 44 U.S.C. 3301), records are: "...books, papers, maps, photographs, machine readable materials, or other documentary materials, regardless of physical form or characteristics, made or received by an agency of the United States Government under Federal Law or in connection with the transaction of public business and preserved or appropriate for preservation by that agency or its legitimate successor as evidence of the organization, functions, policies, decisions, procedures, operations, or other activities of the Government or because of the informational value of data in them...." This section will define GLNPO's document control and records procedures.

5.1 MANAGEMENT OF DOCUMENTS AND RECORDS

GLNPO has centralized the office function to manage documents and records by establishing a staff role, the document control coordinator (DCC). The staff member that fulfills this role is within the Communications and Reporting Team in Policy Coordination and Communications Branch. This document control coordinator is responsible for the following activities:

- ▶ Coordinating assignment of EPA document numbers,
- ▶ Conducting review of documents as requested, and
- ▶ Maintaining inventory of all GLNPO documents with EPA numbers.

POs are responsible for submitting deliverables associated with an EICAA (planning documents, progress reports, final reports etc.) to the DCC for entry into the system. The DCC also will maintain submitted copies of these deliverables in central marked files for proper storage and protection from degradation. Soft-copies are maintained on GLNPO's local area network (LAN). Backups of the LAN are made periodically and maintained offsite. Document preparation, review, and approval will be dependent upon the type of document being produced. For example, an internal document will have different preparation, review, and approval requirements than an external document. The process befitting each document will be determined by the task leader and immediate supervisor. The process for quality system documentation is discussed in Section 2.

5.2 VERSION CONTROL

In order to ensure that GLNPO staff and involved parties are using current documents, GLNPO uses version control procedures that are consistent with ISO 9000 for documents that support critical activities. Currently, these include: 1) this Quality Management Plan, 2) the SOP document in support of GLNPO's base monitoring program, *Sampling and Analytical Procedures for GLNPO's Open Lake Survey of the Great Lakes*, and 3) the GLNPO *Health, Safety, and Environmental Compliance Manual*. GLNPO's procedure involves placing these controlled copies in blue binders for easy identification. Controlled copies of a particular document will be provided to individuals with signature approval for

that document. All GLNPO staff are informed of this procedure during GLNPO's training on the quality management system. POs are responsible for ensuring that all relevant parties involved in EICAA's are aware of GLNPO's controlled copy policy to ensure they locate the current document when needed. When a new version of a controlled documents is created, a summary of revisions will be maintained with the controlled copies.

5.3 INFORMATION QUALITY GUIDELINES

Recently, EPA developed Information Quality Guidelines to comply with an Office of Management and Budget (OMB) guideline (FRL-7157-8, March 2002). Section 515 of the Treasury and General Government of Appropriations Act for FY2001 (Public Law 106-554) directed OMB to issue guidelines that "provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information, including statistical information, disseminated by Federal agencies." EPA posted the final EPA Information Quality Guidelines (IQGs) on October 2, 2002 on OEI's website. GLNPO believes their procedures will enable them to comply with these guidelines and it is GLNPO's goal to implement these guidelines as appropriate throughout the program. Implementation of the requirements specified in these guidelines will be administered through GLNPO's quality system. Specifically, the Information Quality Guidelines will be implemented through the Communications and Reporting Team. The Team Leader for the Communications and Reporting Team will serve as the Divisional Tracking Contact and a Primary Consultant for this initiative. The Team Leader will be supported by the Document Control Coordinator, whose role at GLNPO was established this year (see Section 5.1). GLNPO's Quality Manager will serve as a IGQ primary consultant and also as the IQG Trainer. Training on IQGs will be included in the training course, *Overview of GLNPO's Quality System*, discussed in Section 3. GLNPO will report on the status of this implementation in the QA annual report and workplan.

5.3.1 STANDARD OPERATING PROCEDURES FOR PRE-DISSEMINATION REVIEW

As part of the implementation of IQGs, GLNPO is developing standard operating procedures for pre-dissemination review of GLNPO documents subject to the guidelines. These procedures will include an approval process of pertinent documents by the GLNPO Director. The GLNPO Director may request that other GLNPO staff with applicable experience, such as Team Leaders and the GLNPO Quality Manager, participate in the review of particular documents, as he deems necessary. Formal peer review, as discussed in Section 7.3, also may be part of the pre-dissemination review procedures. Currently, GLNPO plans to track pre-dissemination review in GLNPO's Project Tracking Database described in Section 2.6.

5.3.2 STANDARD OPERATING PROCEDURES FOR REQUEST FOR CORRECTION

GLNPO is developing standard operating procedures for requests for correction (RFC) pertaining to GLNPO documents. A response to an RFC will be processed within 90 days of receipt. If a correction is made, the GLNPO Director will provide signature approval of the correction. If the correction is denied, substantiation to defend the decision will be signed by the GLNPO Director. Currently, GLNPO plans to track requests for correction in GLNPO's Project Tracking Database described in Section 2.6.

Section 6

Information Management

EPA's Office of Environmental Information (OEI) manages EPA's information technology policy, infrastructure, and oversight of Federal and Agency information technology statutes, regulations and standards. With Agency Directive 2100, *Information Resources Management Policy Manual*, EPA established a policy framework for information management at EPA. This manual defines information resources management as encompassing activities associated with planning, budgeting, organizing, directing, and controlling information. GLNPO's efforts to manage environmental information will comply with Agency Directive 2100 and employ this manual and other guidance and planning documents developed by OEI. In addition, all information management system development, enhancement, and modernization efforts comply with the most recent versions of the *System Design and Development Guidance* (EPA Directive 2182, April 30, 1993) and the *Operations and Maintenance Manual* (EPA Directive 2181, April 1990) available from the Office of Environmental Information. The IRM policy, standards, guidance and planning documents are listed on OEI's website.

As GLNPO's information needs expand, the Office must develop and maintain hardware, software, and information systems that efficiently support GLNPO environmental information collection activities and are compatible with Federal and State agencies. GLNPO's Information Management and Data Integration (IMDI) Team leads development and implementation of GLNPO's information management policy.

6.1 GLNPO INFORMATION MANAGEMENT SYSTEM

The IMDI Team provides leadership and support to GLNPO and other involved parties in the storage, access, and retrieval of Great Lakes environmental information. The IMDI Team is responsible for:

- defining GLNPO information management policy,
- developing and maintaining information management systems (e.g., hardware, software, and networks),
- ensuring conformance with EPA and Federal information management policy,
- reviewing and processing hardware and software requests,
- providing technical support to operate information management systems,
- serving as the contact point for electronic data dissemination,
- supporting specialized processing requirements (GIS, remote sensing), and
- providing database administration and management.

The IMDI Team oversees and coordinates all information management activities at GLNPO. The IMDI Team assists GLNPO project planners with communicating pertinent details of GLNPO's Information Management Systems to parties involved in GLNPO-funded EICAA's and facilitating their use. These systems are made available so that States, agencies, and organizations involved in GLNPO EICAA's can implement them if desired.

Most GLNPO employees transfer and retrieve information electronically through the use of personal computers (PCs). GLNPO PCs are linked to a number of communications packages. All GLNPO PCs are linked through local area networks (LANs). This allows a number of PCs to be grouped together to provide a means for sharing information, applications, and equipment such as printers and plotters.

Central to GLNPO's information management system is a computerized database system to house environmental monitoring data. The system was developed and initially implemented to support the Lake Michigan Mass Balance Study (LMMB) and is now supporting aspects of GLNPO's Base monitoring program and other special studies. The Oracle-based system, the Great Lakes Environmental Monitoring Database (GLENDa), was developed to provide data entry, storage, access, and analysis capabilities to meet the needs of GLNPO staff, LMMB study modelers, and other potential users of Great Lakes data.

Development of GLENDa began in 1993, based on the user requirements and logical design from US EPA's STORET modernization project. The close association with STORET has limited the duplication of effort common to database development projects, and ensures maximum portability to the future central home of most environmental data. GLENDa was developed with the following guiding principles:

- **True multi-media scope** — water, air, sediment, taxonomy, fish tissue, fish diet, and meteorology data can all be housed in the database,
- **Data of documented quality** — data quality is documented by including results of quality control parameters,
- **Extensive contextual indicators** — ensures data longevity by including enough information to allow future or secondary users to make use of the data,
- **Flexible and expandable** — the database is able to accept data from any Great Lakes monitoring project, and
- **National-level compatibility** — GLENDa is compatible with STORET and allows ease of transfer between these large databases.

During GLNPO's Water Quality Survey (WQS) of the Great Lakes in Summer 2000, GLNPO began phasing in the use of an on-board GLENDa data entry system designed to capture data directly into the database on a daily basis. The purpose of this pilot was to test the entry system as a means of facilitating streamlined upload of survey data to GLENDa and dissemination of survey results to interested parties. The data entry system is available on the Lake Guardian and also at GLNPO headquarters. The data entry system can be used for real-time data entry or by entering data recorded on hard-copy data forms. The system is designed to include real-time data entry checks to prevent analysts or technical staff from entering 'nonsensical' values.

The WQS Chief Scientist has primary responsibility for assuring that all data gathered in the survey are documented. Documentation includes raw instrument level printouts, summary bench sheets, and electronic records generated on board ship and in the laboratories. All shipboard-generated strip charts, bench records, and computer printouts are kept in a folder, indexed by station, until the remaining samples are transferred to involved laboratories. All raw data are assembled and indexed by parameter, by lake, and by survey leg. All onboard results will be recorded in the GLENDa data entry system, or on hard-copy or soft-copy data forms for subsequent entry into the onboard system. These files will be transferred to a CD or floppy diskettes.

For extramural programs, GLNPO POs are responsible for obtaining all appropriate data derived from GLNPO-funded EICAAs. At the time of project planning, the data reporting requirements, including the type of data (raw, verified, QA/QC), and the media (paper, electronic, disk, tape etc.), must be explicitly determined and documented in the quality system documentation. It is highly recommended that all environmental monitoring data funded by GLNPO be reported according to the data reporting standards (Section 6.3).

6.2 HARDWARE AND SOFTWARE REQUIREMENTS

The IMDI Team ensures that GLNPO is conforming to all Federal and EPA standards for hardware and software and in-house information management systems. The Office of Environmental Information develops standards for EPA data processing and telecommunications. They also provide technical assistance and advice to EPA and State agencies concerning the acquisition and implementation of information management technology. As part of this assistance, EPA developed an information technology architecture road map that establishes the Agency's information technology portfolio, as required under the Information Technology Management Reform Act of 1996. The road map forms the basis for the selection and deployment of computing platforms and network connectivity between computing platforms, as well as the software and related products that interconnect computing platforms. GLNPO conforms with this road map when purchasing hardware and software. In addition, GLNPO complies with the *Delegation of Procurement Authority Guide* to ensure that purchased software will meet user requirements and will comply with the Office of Environmental Information standards. The IMDI Team relies on guidance and planning documents developed by OEI on technology infrastructure to purchase and manage information technology systems.

IMDI regularly conducts user needs assessments of GLNPO staff to identify when additional infrastructure is needed. Once a need is defined, the IMDI solicits various vendors for software demonstrations. Only vendors that comply with Agency information resources management standards are solicited. The IMDI, as well as appropriate GLNPO staff, evaluate the software to determine its performance and future capabilities. Prior to purchase, the IMDI Team fully evaluates software in terms of its intended use. Software is selected on the basis of minimum performance standards and cost.

Software also may be developed in-house and may involve smaller, specialized information systems that could include small databases, spreadsheets, and data entry tools. Many of these systems are based on commercially-available software and may only be employed for short periods. In these cases, the information system standards may not be applicable and may do little to ensure the quality of those systems. GLNPO's graded approach applies to planning and documentation of software development. The PO and the Branch Chief are responsible for identifying when such "minor" information systems will be employed and documenting all efforts by the project staff to ensure their quality. Project documentation should include a detailed description of the algorithm or software process used in the project. For larger scope software development projects proper documentation must be developed that includes:

- ▶ hard-copy documentation of the software,
- ▶ the developer's name,
- ▶ the names of all current maintenance personnel,
- ▶ intended use of the software package (capabilities & non-capabilities),
- ▶ the detailed process used to verify the software, including test examples, and
- ▶ software code with sufficiently detailed comments to ensure understanding by other analysts or programmers according to EPA coding policy.

A formal quality management process must be developed for complex software development projects (e.g., mathematical models). Prior to initiation of these projects, GLNPO staff must prepare planning documentation that includes a section devoted to the quality management of the software system. The documentation should address the planning, budgeting, organizing, directing, and training needs associated with the software development project. The planning documentation also should address audits and tests of the software at various phases to assure the integrity of the software.

6.3 REPORTING STANDARDS

In order to be capable of utilizing information across GLNPO programs and between other EPA Regions and laboratories, emphasis must be placed on improving information compatibility. The EPA Data Standards Program is established and documented in EPA Directive 2100 *Information Resources Management Policy Manual*. GLNPO adheres to this program and all mandatory Agency data standard policies.

GLNPO devised reporting standards for data submissions for their EICAAs in accordance with Agency policy. GLNPO's data standards are designed to ensure consistency in reporting and facilitate data verification, data validation, and database development. GLNPO's data standard conforms to the QA/QC codes as derived from EPA Order 2180.2 Appendix B. To date, GLNPO has developed standards for the following data: air/water analyses, fish tissue, fish diet, and sediments. The latest reporting standards are available at the following web page: <http://www.epa.gov/glnpo/lmmb/rptstds/index.html>. This site will be updated periodically as the reporting standards are changed. The reporting standards also can be requested from GLNPO for transfer by disk or e-mail. Examples of GLNPO's data reporting standard and QA/QC codes are listed in Appendix D.

The Field Reporting Standard contains information about the station visit, sample collection activities, and results from *in situ* measurements and visual observations. Generally, it is used to record information about what was collected, where it was collected, how it was collected, by whom it was collected, and the results of field measurements and observations. The Laboratory Reporting Standard contains information about laboratory samples and analyses. Generally, it is used to record information about the analysis of field and QC samples and the results obtained from such analyses. To capture all of this information in a logical and useful way, the Reporting Standard is broken into several files - most of which are used only in special cases.

Data reporting requirements must be consistent with GLNPO and Agency information management policy. POs are responsible for the format, quality and submittal of data derived from GLNPO funded EICAAs. At the time of project planning, the type of data (raw, verified, QA/QC), and the media (paper, electronic, disk, tape etc.) must be determined. A data submission is defined as a logical combination of Reporting Standard files that are sent as a unit from an investigator to GLNPO. Each submission is defined within a field delivery header file that contains a unique combination of project code, sampling organization code, submission number, and version number. The submission number and version number are assigned by the investigator for tracking purposes. The version number is simply a control number that distinguishes a specific collection of data from older (or newer) submissions of the same data. The data submission concept becomes important when an investigator determines that he/she needs to replace a data submission that was sent previously to GLNPO. An investigator easily can replace a data submission by sending an updated, complete data submission that is identified with the same submission number as the original data but with an incremented version number.

6.3.1 GLNPO LOCATIONAL DATA POLICY

IRM Policy Manual 2100 Chapter 13, requires geographic coordinates and associated method, accuracy, and description codes (MAD) for all environmental measurements collected by EPA employees, contractors, and grantees. This policy establishes the principles for collecting and documenting latitude/longitude coordinates for facilities, sites, and monitoring and observation points under Federal environmental programs. The intent of this policy is to extend environmental analyses and allow data to be integrated based upon location, thereby promoting the enhanced use of EPA's extensive data resources for cross-media environmental analyses and management decisions. This policy underscores EPA's commitment to establishing the data infrastructure necessary to enable data sharing and secondary data use. To facilitate the integration of data into these systems it is important that coding of geographic coordinates and associated attributes be standardized. All GLNPO projects that include data collection, habitat restoration, or other 'location dependant' activity are required to adhere to GLNPO's Locational Data Reporting Format, both intramural and extramural. The GLNPO Locational Data Reporting Format is compliant with the Region 5 and Headquarters Locational Data Policy and was approved by the Region 5 Locational Data Manager. The GLNPO Locational Data Reporting Format is available on the GLNPO web page <http://www.epa.gov/glnpo/fund/ldp.html>.

6.4 INFORMATION SECURITY

GLNPO has developed an information security plan to manage security controls of GLNPO's LAN, named Great Lakes National Program Office Binational and Partner Network (GLNPO.net). The purpose of GLNPO.net is to provide a development/production Internet site available for web projects that are binational or regional in scope without putting the US EPA network at risk. The system supports 50 developers, including GLNPO, Region 5, US Army Corp of Engineers, State and Environment Canada staff and their contractors, as well as EPA grantees and cooperators. GLNPO is responsible for development and implementation of the system. The users that view pages on the site range from GLNPO partners (using "user IDs" and passwords) to the public, who are directed to a particular URL, depending on content. The system is located at in the Metcalf Federal Building in Chicago, Illinois.

The Information Security Plan is maintained by the Information Management and Data Integration Team who are responsible for implementation of the plan. Specifically, Pranus Pranckevicius¹, the Team Leader, maintains the plan. A cover page of the December 2000 draft of the Information Security Package is included in Appendix E that includes authorizations for the plan and the table of contents for the Information Security Package. In the plan, GLNPO documents assignment of responsibilities associated with the development and implementation of GLNPO's system security as well as user responsibilities. GLNPO included in the plan the rules for accessing GLNPO.net and using GLNPO data. The plan also includes information on training individuals to use the system and on security awareness in general. GLNPO also details management of personnel controls for the system and incident response activities. Confidentially sensitive data are not permitted on GLNPO.net. GLNPO is developing this system in accordance with the following laws and regulations:

- The Computer Security Act of 1987,
- Privacy Act,
- OMB Circular A-130, *Management of Federal Information Resources*,
- EPA *Information Resources Management Policy Manual*, and
- the *Enterprise Technology Services Division LAN Operating Procedures Manual*.

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Section 7

Quality Planning

In order to accomplish its mission, GLNPO must effectively plan and implement environmental information collection activities. It is GLNPO policy that collecting environmental data of adequate quality for its intended use can only be achieved with systematic planning prior to initiation of an EICAA. Further, GLNPO's quality management policy stipulates that planning processes must be adequately documented. In accordance with GLNPO's graded approach the level of detail in planning and documenting the planning process should be commensurate with the importance and intended use of the work, available resources and unique needs of the organization. The following sections describe the processes GLNPO uses to plan EICAAs and document the planning process.

7.1 PROJECT PLANNING AND SCOPING

Each year, GLNPO conducts planning meetings with local, State, Tribal, Federal, and international Great Lakes stakeholders. From these annual meetings and through Agency direction, Great Lakes environmental issues of concern are identified and funds are reserved for discretionary grants and intramural activities to address these issues. GLNPO Teams then develop and distribute requests for proposals (RFPs) regarding these issues of concern. Once pre-proposals are submitted, GLNPO Teams review them and identify those that are of interest to GLNPO to fulfill their mission. The Quality Management Team assists the POs in distributing to potential grantees a copy of EPA QA/R5, *EPA Requirements of Quality Assurance Project Plans* and pertinent examples of quality system documentation from similar past projects. Potential grantees are encouraged to submit a full proposal based on applicable sections of QA/R5. In this way, the quality planning process begins at the earliest phase of the EICAA and the probability this process will provide added value to the EICAA is greatly increased.

Systematic planning is essential to managing quality and should be conducted by a group with sufficient knowledge to ensure that the activities undertaken will result in a product with the level of quality needed for its intended purpose. The planning steps listed below are one suggested approach that GLNPO POs and task leads can use to plan effectively and meet the requirements of GLNPO's quality system. Although the exact questions illustrated in the planning steps may not need to be answered, the issues behind the questions need to be addressed before proceeding with the activity. A common approach to answering these questions, and thus to planning, is to assemble a team or a work group of knowledgeable staff to address these details. At GLNPO, the functional teams often fulfill this role with their Management Advisor and additional participating staff with a firm technical grasp of the subject matter. In addition, staff that control the budget and those that manage any contractors or grantees involved in the effort also should be included in the group. It is also essential that the team consult with a member of the Quality Management Team to ensure that GLNPO's quality system requirements are being addressed.

Step 1 – Problem Identification

- ▶ What is the problem and how does it relate to GLNPO's mission? (e.g., verbal statements of the general problem can be narrowed into succinct questions that are unambiguous and can be answered with specific data.)

Step 2 – Project Purpose

- ▶ What is the primary purpose of the activity and why is it important to proceed?
- ▶ Are environmental data required?
- ▶ What is the schedule for completion and is it driven by forces outside of GLNPO (e.g., legislative or judicial deadlines)?

Step 3 – Project Design

- ▶ What are the quality requirements for the activity?
- ▶ What is the allowable level of uncertainty? (i.e., quantify the level of uncertainty that will be allowed while still being able to answer the project questions outlined in Step 1.)

Step 4 – Resource Requirements

- ▶ What activities must be performed?
- ▶ What staff members are needed to complete these activities? Are these staff available? If not, what other options exist (e.g., will staffing limitations dictate achievable project quality or project design?)
- ▶ What resources and materials are needed to complete project activities? Are these resources/materials available? If not, what other options exist (e.g., will resource limitations dictate achievable project quality or project design?)
- ▶ If data are required, what kind of data are needed, how will they be collected, and what are the quality requirements?
- ▶ Can we achieve these requirements within the schedule, using the available technical, financial, and staffing resources?

Note: Quality management is an integral part of any GLNPO EICAA and should be included as a budget line item.

Step 5 – Roles and Responsibilities and Project Products

- ▶ Who is the customer and what are their expectations (e.g., senior EPA management, the public, Congress, the regulated community, etc.)?
- ▶ What types of information does the customer need (i.e., summary information, detailed trends, graphs, GIS etc.).
- ▶ Who is the supplier and what are their responsibilities? (i.e., personnel responsible for management, planning, budgeting, reporting, etc. must be clearly identified in the planning documentation.

Step 6 – Performance Measures

- ▶ How can we measure the success of the project (e.g., through quantitative measures, surveys, peer review, etc.)?

Note: The measure of success is an important aspect of the assessment and corrective action phases of the project, which are discussed in Section 9.

Upon completion of these steps, it should be clear whether the questions can be answered with the resources available and at the desired level of uncertainty. The project leads may have to choose between adding more resources or having less confidence in the data. In summary, systematic planning involves determining and clearly defining your objective and developing a detailed plan to address the objective that considers available resources that are allocated to support it.

At GLNPO, the Quality Management Team is involved in planning EICAAs. The Team will assist POs and task leads by identifying necessary quality management activities for a given project. The Quality Management Team generally assists in:

- developing quality system documentation,
- implementing the quality system,
- conducting audits and system reviews,
- providing technical support to determine needed QC samples, and
- assessing data quality.

In order to ensure that quality system requirements are considered for *every* EICAA, the Quality Manager reviews every expenditure for extramural projects to determine if quality system documentation and peer review are needed for that project to meet GLNPO's quality policy. A Project Inventory and Approval Form (Appendices H and I) accompanies assistance (grant and IAG) packages and serves to document the Quality Manager's determination of whether quality system documentation or peer review are needed for a given project. GLNPO senior management does not approve of expenditures without a project inventory and approval form containing the approval signature of the Quality Manager or his designee from Quality Management Team. This is a key part of GLNPO's quality system because it is the first step in the inventory of all EICAA's at GLNPO. The Quality Management Team and POs can employ a series of checklists to assist them in making this determination. The Quality System Documentation Checklist provided in Appendix F can be used to guide POs, line management and the Quality Management Team through the process of planning a project while complying with GLNPO's quality system.

If the project requires quality system documentation, the Quality Management Team begins tracking the EICAA by entering information regarding the project into GLNPO's tracking database, QATRACK. The Quality Management Team uses QATRACK to provide the status of EICAAs and associated required quality system documentation to GLNPO staff and management at monthly meetings. In addition, the database assists the Quality Management Staff in notifying POs when required documentation is overdue. Once the documentation is overdue, GLNPO's *Protocol to Address Missed Requirements* is implemented (Appendix M). The protocol addresses the failure of funded entities to provide quality system documentation and other required work products on schedule by providing a general framework for action including how and when to involve management. This protocol involves notifying the PO of the delinquency through a written memo from the Quality Management Team. An example of this memo is provided in Appendix N.

7.2 DOCUMENTATION

Another critical component of GLNPO's quality system is that the planning process must be documented. The information generated during the six planning steps listed above forms the basis of the quality system document. GLNPO recognizes that documentation of the project is of utmost importance and must address all phases of the EICAA. While the data from a project may be technically sound, lack of proper documentation can make the data suspect and the defense of a project difficult if not impossible. Documentation must address all phases of the EICAA.

Quality system documentation can be developed in a variety of forms. Two of the most common forms are a quality management plan such as this one, and a quality assurance project plan for an activity involving the collection of environmental data. The reference section of this document contains the titles of the latest guidance and requirements documents for those plans that are available from the EPA Quality Staff. These plans do not apply to every decision-making activity that may be conducted by or for GLNPO, and may apply poorly to others.

Therefore, GLNPO's quality system explicitly provides for a graded approach to the documentation of environmental data collection activities. The most stringent approach to such documentation is a quality assurance project plan as described in EPA QA/R-5. However, the planning process may be used to specify when other forms of documentation will be employed. For example, GLNPO funds a variety of grants to States, Tribes, and public and private organizations that advance its mission. Some of those grants involve the collection of environmental data, but are for small dollar amounts that simply cannot support the production of elaborate quality system documents such as quality assurance project plans. Other intramural activities involve the collection of environmental data that are never going to be used to make an environmental decision, but rather are used as a means to raise public awareness of environmental issues or provide educational outreach. Therefore, these data collection activities need not be documented in a format as formal as a quality assurance project plan. For other projects, a document addressing all components of QA/R-5 is appropriate. For example, GLNPO has developed a QAPP in accordance with EPA QA/R-5 for the base monitoring program that is updated annually by POs and the Quality Management Staff. GLNPO's graded approach will rely on EPA R-5 to form the basis for quality system documentation and will require documentation that addresses applicable components of EPA QA/R-5 for all GLNPO-funded EICAAs.

According to the *EPA Quality Manual for Environmental Programs*, the eight elements of the planning process listed in Exhibit 6 must be documented. The specific details of these elements are addressed in the six suggested planning steps described in the previous section. Whatever form of documentation is used, it must address these elements of the planning process.

Exhibit 6
Eight Elements of the Planning Process That Must Be Documented

1. Identifying the project manager, the sponsoring organization and the responsible individual within that organization, the project personnel, the "customers" and "suppliers," and describing their involvement in the project.
2. The project goal, objectives, and the questions and issues to be addressed
3. The project schedule, resources and budget, and milestones, and any applicable requirements (e.g, regulatory or contractual requirements)
4. The type of data needed and how those data will be used to support the project objectives
5. How the quantity of data needed was determined and how the criteria for the quality of the data were determined
6. How, when, and from where data will be obtained, including existing data. Identifying any constraints on the data collection process
7. Specification of the activities during data collection that will provide the information used to assess data quality (i.e., field or laboratory quality control operations, audits, technical assessments)
8. How the data for the project will be analyzed, evaluated, and assessed against their intended use and the performance criteria established above.

It is important to establish efficient communications among all project participants to ensure smooth operation of all phases of an EICAA. A "Project Organization" section in the quality system documentation helps to establish the lines of communication.

For projects or tasks involving environmental data performed through grants and cooperative agreements (40 CFR Parts 30, 31, and 35), the planning process *must* identify the appropriate level of quality system documentation that will be employed. The documentation must be reviewed and approved by the relevant POs, task leads, and the Quality Management Team prior to the start of EICAAs.

When working with States that have GLNPO-approved QMPs, approval authority for quality system documentation for EICAA's under their supervision is delegated to the State. The PO can review quality system documentation to ensure that the technical requirements of the project are clearly met; however, approval of the quality system is delegated to the State. The States often request that GLNPO review and provide input on quality system documentation. GLNPO routinely offers its support and is committed to working with States in the Great Lakes Region to effectively plan and implement EICAAs.

For projects that employ data from other sources (i.e., secondary data), the level of quality system documentation should be commensurate with the nature of the data and the decision to be made. The Office of Environmental Information is developing guidance on using data from other sources. When the guidance is finalized, GLNPO will review it and, if appropriate, incorporate the guidance into the procedures for assessing the quality of secondary data. In the meantime, GLNPO will continue to use

the planning process described in this plan to identify when secondary data will be used, to establish acceptance criteria for the data, and to outline the manner and extent to which secondary data will be verified. The project staff will continue to employ professional judgement to ensure that the data meet the needs of the project.

Once quality system documentation is submitted, the PO reviews the document to ensure that the technical requirements of the project are clearly met. If approved by the PO, the quality system documentation is forwarded to the Quality Management Team for review and approval. The Team employs formal procedures for logging, tracking, and maintaining all submitted documents as described in Appendix S. As part of these tracking procedures, the Quality Management Team uses a Quality System Documentation Status and Tracking Sheet (Appendix O) to monitor fulfillment of documentation requirements. All submitted documents are maintained by the Team in both hard-copy and soft-copy (when available). The Team conducts a standardized review using a checklist to document the acceptability of all applicable requirements and determines that quality requirements are:

- included and acceptable,
- included and not acceptable,
- not included,
- not applicable.

The checksheets, one for reviewing QAPPs, and one for reviewing QMPs, can be found in Appendix J. After completing the review, the Quality Management Team provides a cover memo and check sheet with comments to the PO detailing conclusions, recommendations and any required revisions. When revisions are needed, the documentation is resubmitted and reviewed by the Team. GLNPO's Quality Manager is available to assist involved parties with understanding and meeting the quality system requirements and often participates in meetings or conference calls if requested by the PO.

As part of project planning, project leaders will develop timelines for the development, review, and completion of required documentation. Appropriate reviewers of documentation also should be identified as part of the planning process. Documents will be archived as detailed in Section 5.

7.2.1 GLNPO'S GRADED APPROACHES TO QUALITY SYSTEM DOCUMENTATION

GLNPO implements a graded approach to quality system documentation that is consistent with the decision being made. Every expenditure that GLNPO makes towards EICAAs and every intramural project that collects environmental information driven by environmental decisions should have quality system documentation commensurate with the importance of the question that is being addressed. A small environmental education grant will not need as much documentation as a large monitoring program involving several agencies and large-scale sampling. **At a minimum, all projects that collect environmental information should default to quality system documentation in accordance with EPA Requirements for Quality Assurance Project Plans (EPA QA/R-5), addressing all applicable components.** Typically, GLNPO will accept a QAPP as sufficient documentation of the quality system. In other cases, when providing funds to one organization that will in turn provide those funds to another organization, a QMP is required. However, QMPs are not required for all of GLNPO's extramural projects. Available resources also are a consideration, such as when working with Tribes. In these cases, GLNPO will work more closely with organizations that do not have the infrastructure to support a large-scale quality system.

The Quality Manager, in conjunction with Project Officers, will determine the appropriate level of quality system documentation for each project. In the past, GLNPO has used a four-tiered project category approach to determine the detail necessary for QAPPs (GLNPO QMP, October 1997, Revision 03). These categories have been replaced by the eleven categories listed in the table below.

Categories of Environmental Information Collection and Assessment Activities	
State agencies	<i>Quality system documentation at the program-level is most often required (QMPs)</i>
Consortium grants	
Cluster grants	
Repeating projects of similar scope	
Existing data/modeling	<i>Quality system documentation at the project-level is most often required (QAPPs)</i>
Tribal grants	
Sediment assessment	
Habitat/Ecosystem restoration	
Ambient monitoring and research demonstration	
Pollution prevention and Environmental education	
Volunteer monitoring	

Suggestions and requirements for quality system documentation for each of these categories are discussed in detail in the following sections. In some cases, categories identified as most often requiring project-level documentation may be better suited to program-level documentation. This will be determined on a case-by-case basis by GLNPO's Quality Manager. Quality system documentation for programs is discussed in Section 7.2.1.1 and quality system documentation for projects is discussed in Section 7.2.1.2. Examples of GLNPO's graded approaches for quality system documentation are included in Appendix K

7.2.1.1 QUALITY SYSTEM DOCUMENTATION FOR PROGRAMS

GLNPO often funds other organizations that conduct or oversee EICAAs. These activities fall into four general categories: 1) consortium grants, 2) cluster grants, 3) state agency funding, and 4) funding repeating projects with similar scope and common elements. Consortium grants include large studies with multiple grantees and sub-grantees addressing a single issue. For example, GLNPO issued a consortium grant for Lake Erie where many experts were assembled to address the single issue of oxygen depletion in the lake. Cluster grants generally involve one organization that administers multiple projects. GLNPO regularly administers funds to States around the Great Lakes covering a multitude of projects. Repeating projects of similar scope are a unique type of agreement. They include projects where GLNPO works with an approach or standard operating plan developed by a lead agency, such as The Nature Conservancy, where multiple projects are administered individually through various grantees.

For groups that are working with GLNPO in one of these categories, GLNPO expects the grantee organization to have a quality system in place that is consistent with ISO 9001 and EPA Order 5360.1 A2. For major programs, *EPA Requirements for Quality Management Plans* (EPA/QA R-2) must serve as the basis for quality system documentation. A list of components of a quality management plan

according to EPA QA/R-2 is provided in Table 1 at the end of this section. All of the project planning documents, quality system documentation, and products of the projects are subject to GLNPO review and approval. Quality system documentation for specific projects including QAPPs and SOPs must be provided to GLNPO upon request to facilitate a technical system or a quality system audit. Many POs at GLNPO request project-specific documentation in order to get an idea of the technical direction and adequacy of specific projects, but they do not serve in an approval capacity.

Once a quality management plan is approved, GLNPO will not micro-manage organizations or agencies. GLNPO understands that time is needed to implement a true functioning quality system. GLNPO will request quality system documentation only for specific instances in order to review technical correctness and will not review documentation as a matter of course.

GLNPO's Quality Management Team will provide training on development of quality systems as requested.

A true functional value-added quality system is not driven by approved documentation, but more so, by the activities implemented on a daily basis that enhance the quality of the environmental decision.

GLNPO administers funds to eight States around the Great Lakes: Minnesota, Wisconsin, Michigan, Ohio, Indiana, Illinois, Pennsylvania, and New York. Currently, GLNPO only recognizes the quality management system implemented by the State of Wisconsin. For states that have obtained EPA Regional approval of their quality management system, GLNPO will recognize this approval, as long as the scope of GLNPO activities that the State is involved in is addressed in the quality system. GLNPO is interested in working with each State to develop an approved quality system and will offer assistance when requested.

Quality management resources often are lacking at the State level. In these cases, GLNPO may provide assistance for reviewing quality system documentation and other quality management areas as requested by the State. In some cases, grants to State agencies fit into the cluster grant category and are termed performance partnership agreements.

The quality system documentation requirements for the remaining three program-level categories are further described below.

7.2.1.1.1 CLUSTER GRANTS

GLNPO issues a large number of grants, many of which are quite small, and the administrative burden can exceed GLNPO's ability to effectively oversee and implement the projects. GLNPO uses cluster grants to coordinate groups of grantees and sub-grantees. For example, GLNPO often administers one cluster grant to the Great Lakes Commission which provides grants to 3 different agencies. In these agreements, GLNPO expects that project-level quality system documentation will be reviewed by a trained quality manager. The principle investigator also can review the quality system documentation for technical correctness and GLNPO encourages this procedure. The quality system documentation for cluster grants must include detailed information regarding the review procedures for project-level quality system documentation. This detailed information should discuss what is expected in project-level quality system documentation, the procedures that will be implemented to review the quality system documentation, and the roles and responsibilities of involved parties regarding the review and approval of the project-level quality system documentation. The GLNPO Quality Management Team can assist grantees with training for reviewing quality system documentation and can assist in the review, if requested. Grantees should conduct a quality system audit at least once during the project, preferably

close to the start of the project. Details of how this assessment will be conducted and who is responsible for ensuring that it is conducted also should be included in the quality system documentation. Cluster grants require regular coordination among quality managers at grantee and sub-grantee organizations and GLNPO.

7.2.1.1.2 CONSORTIUM GRANTS

Consortium grants are similar to cluster grants, except that groups of grantees are focusing on one key question. The quality system documentation requirements are the same as for cluster grants, however, the focus is on the over-arching quality management plan, whereas for cluster grants, the focus is on project-specific quality system documentation. Other than this difference in focus, the quality system documentation requirements are the same for consortium grants as they are for cluster grants. The *Great Lakes Commission Quality Management Plan* is provided in Appendix K as example documentation for a consortium grant.

7.2.1.1.3 REPEATING PROJECTS OF SIMILAR SCOPE

GLNPO works with various non-governmental organizations that conduct projects of similar scope with a variety of grantees. For example, GLNPO often enters into agreements with The Nature Conservancy. In implementing projects, each grantee uses standard procedures developed by The Nature Conservancy that include:

1. Data dictionary,
2. Data reporting procedures,
3. Data use and security restrictions, and
4. Standard operating procedures for species identification and abundance measures.

GLNPO encourages organizations that implement these types of projects to develop a single quality system document to cover all of these types of activities in order to save resources needed to develop and review multiple quality system documents. A quality management plan at the national level will ease the administrative burden at the local level. GLNPO will assist these organizations in developing program-level quality system documentation. A generic quality assurance project plan for the repeating projects also may be appropriate. In these cases, additional event-specific documentation, such as a sampling and analysis plan that documents specific information that is not addressed in the generic QAPP, may be sufficient

Table 7-1. Required Elements in a Quality Management Plan (QMP)

Elements	Requirements
A1 Management and Organization	Give an overview of
A2 Organization's QA Policy Statement	State the importance of QA and QC, general objectives/goals of Quality System, and policy for resource allocation for the Quality System.
A3 Distribution List	Distribution list for the QMP revisions and final guidance.
A4 QA Manager/Staff Authorities	Discuss the responsibilities and authorities of QA Manager and other QA staff; document independence of QA Manager
A5 Technical Activities/Programs	Discuss specific programs that require quality management controls, where oversight of extramural programs is needed to assure data quality, and where internal coordination of QA and QC activities needs to occur.
B1 Quality System Components	Describe the organization's quality system
B2 Principle Components	Discuss the principal components (quality system documentation, annual systems review, management assessments, etc.) which comprise the quality system
B3 Tools for Implementing Components	QMPs, management assessments, technical assessments, systematic planning, SOPs, QAPPs, and data quality assessments
C1 Personnel Qualifications & Training	Describe organization's training policy, processes, and documentation.
D1 Procurement of Items & Services	Describe the roles, responsibilities, and authorities of management and staff which pertain to all appropriate procurement documents or extramural agreements
D2 Procurement Document Approval	Describe review and approval procedures for procurement documents
D3 Solicitation Response Approval	Describe review and approval processes of all applicable responses
E1 Documents and Records	Discuss procedures for documents and records
F1 Computer Hardware and Software	Describe QA and QC processes for the use of computer hardware and software to support environmental data operations
G1 Planning	Describe systematic planning process for environmental programs, discuss QAPP process, and discuss organization's secondary data policy
H1 Implementation of Work Processes	Describe developing and implementing procedures, planned procedures, and controlling measures
I1 Assessment and Response	Describe how and by whom assessments of environmental programs are planned, conducted, and evaluated; and the processes by which management determines assessment activities and tools appropriate for a particular project and expected frequency of use
J1 Quality Improvement	Describe how organization will detect and prevent quality problems and ensure continual quality improvement; communication of expectations about quality improvement to staff

GLNPO added note: The above elements are the minimum requirements for a QMP, and therefore, should be used during the QMP development.

7.2.1.2 QUALITY SYSTEM DOCUMENTATION FOR PROJECTS

GLNPO's environmental information collection activities typically fall into the seven categories listed in 7.2.1. Quality system documentation for these activities will vary according to the characteristics of the specific projects in accordance with GLNPO's graded approach, such as the impact of the decision, the cost of the project, and the project objective. The required documentation for all the following categories must be based on EPA QA/R-5. A list of the components of quality system documentation according to EPA QA/R-5 is provided in Table 2 at the end of this section. However, all components will not apply to all projects. Suggestions for quality system documentation for the seven general categories are further described below.

7.2.1.2.1 EXISTING DATA/MODELING

GLNPO environmental information activities can involve modeling and the use of existing data. Project planning for modeling projects is important in order to ensure that the model is scientifically sound, robust and defensible. EPA's Quality Staff has developed a guidance document (EPA QA/G-5M) that can provide assistance in planning and implementing modeling projects. Additionally, EPA's Quality Staff also has developed a draft checklist, *Using Data from Other Sources - A Checklist for Quality Concerns*, for use in planning modeling and other projects using existing data. The checklist includes the following steps (adapted by GLNPO):

1. Identify the decision you are making or the project objectives.
2. Identify the data and information from outside sources proposed for the project.
3. Prioritize data needed for decision (i.e., what are the most important pieces of data).
4. Determine whether the data have any constraints affecting their use in the new project.
5. Determine where the acquired data will be used in the decision-making process.
6. Scrutinize data for quality concerns pertinent to the intended use.
7. Document your analysis plan.
8. Execute your analyses and document the outcome appropriately.

A past GLNPO modeling project, Lake Erie Total Phosphorus Loads, illustrates how the checklist can be used for planning and documenting a project (see Appendix K). An example of quality system documentation for modeling, *Quality Assurance Project Plan for Lake Erie Total Phosphorus Loads: 1996 to 2000*, also is provided in Appendix K. In addition, an example of quality system documentation for secondary data, *Quality Assurance Project Plan for Great Lakes Sediment Data Support*, is provided in Appendix K.

In general, for modeling projects and projects that use existing data, the expertise of personnel involved in the modeling effort is of utmost importance. Curriculum vitae and resumes of key personnel should be included with the quality system documentation. Roles of involved personnel and their expertise is critical due to the subjective components of model development and application. Experts that are needed to provide related technical assistance, such as chemists, also must be identified in the documentation.

For modeling projects and other projects that use existing data, a QAPP based on the applicable components of EPA QA/R-5 would be considered sufficient to define the appropriate quality system. For modeling projects, the importance of having all of the quality system documentation finalized prior to initiation of the project is not as great as it is for other types of projects (such as when cost constraints involved with sampling efforts require thorough documentation prior to sampling). GLNPO understands that for modeling projects, much of the planning will depend on the outcome of the initial efforts that

involve evaluating existing models and available data. For this reason, the documentation could be developed in steps, given the evolution of the modeling effort. Documentation with as much detail as practical should be developed prior to initiation of the project. Thorough quality system documentation that addresses other components of the project could be developed in the mid-stages of the project, once the initial efforts have provided the final direction of the project. For example, the roles and responsibilities of involved personnel must be documented in detail prior to the initiation of the modeling effort. In addition, the criteria for evaluating data for acceptability into the model also must be documented. Another important component to include in the initial documentation is the methods that will be used to evaluate, assess, and test software and other modeling tools.

For development of new models, comparison of the output to existing models would provide a good assessment tool for the new model. Documentation should discuss these planned activities in addition to planned sensitivity testing of the model and identification of key variables.

7.2.1.2.2 TRIBAL GRANTS

GLNPO administers grants to several Tribes in the Great Lakes region. In some cases, Tribes are characterized by less infrastructure and available resources than many other organizations that work with GLNPO. However, in order to conduct effective projects and make good use of resources, quality assurance issues need to be addressed. Tribal grantees should use EPA QA/R-2 and EPA QA/R-5 as the basis for quality system documentation, while considering the tenet behind the graded approach discussed throughout this document. In fact, tribal grants are one of the driving forces behind the graded approach. GLNPO will implement a flexible approach when reviewing quality system documentation for tribal grants, however, as stipulated for GLNPO's graded approach, quality activities for a given project must be commensurate with the decision that is being made. GLNPO will offer training to tribal grantees when requested and will provide examples of quality system documentation from similar grants when available. GLNPO also encourages coordination among Tribes, so that quality management activities for one project can serve as an example for similar projects.

7.2.1.2.3 SEDIMENT ASSESSMENT

GLNPO conducts three types of sediment assessment projects: 1) assessments which include screening level and site-specific assessments, 2) remediation projects, and 3) post-remediation projects. For GLNPO's sediment assessment grants, GLNPO requests that grantees develop quality system documentation that addresses all components of EPA QA/R-5. Typically, remediation projects will involve more detailed documentation than the other types of projects. Sediment assessment projects use the NOAA Query Manager Database to store and retrieve sediment data. Sediment assessment projects stipulate data reporting in a format specific to the Query Manager Database and the quality system documentation should describe activities that implement this data standard. Details of the database are described in, *The Quality Assurance Project Plan for Great Lakes Sediment Data Support* included in Appendix K. Sediment assessment projects also can involve existing data and the quality system documentation issues described in Section 7.2.1.2.1 are pertinent for these projects. Examples of quality system documentation are provided in Appendix K and include: for assessment, *The Quality Assurance Project Plan for Cuyahoga River Old Channel Assessment*; for site-specific assessment, *The Quality Assurance Project Plan for Raisin River Sediment Sampling in FY2002: A Follow-up to the 1997 Sediment Remediation Project*; and for remediation projects, *Quality Assurance Project Plan for Kinnickinnic River Sediment Sampling in FY2002*.

7.2.1.2.4 HABITAT/ECOSYSTEM RESTORATION MANAGEMENT

Activities supporting habitat and ecosystem restoration management generally fall into three categories: assessment, restoration, and protection. Of these three categories, habitat assessment projects generally require the highest level of data quality. For habitat restoration management projects, quality system documentation should identify the expertise needed to support the project. Expertise involving species identification, detailed knowledge of site conditions, and optimal site conditions associated with target species is very important in habitat restoration and management activities and should be discussed in the quality system documentation. Species identification training for staff supporting the project also should be included and often involves picture or photo keys that staff can use in the field or the lab. Because some of the habitat measures involve subjective measurements, such as percent dieback, photo documentation may be helpful. Random checks on personnel involved in these subjective measures, such as a side-by-side comparison of measurements against qualified personnel can enhance the confidence in the data and if implemented should be discussed in the documentation. Other important considerations for habitat projects that should be included in the documentation include use of geographical standards and proper handling of ecologically sensitive data such as those that involve endangered species. An example of quality system documentation for habitat restoration management, *Quality Assurance Project Plan for Controlling the Spread of Swallow-wort*, is provided in Appendix K.

7.2.1.2.5 AMBIENT MONITORING AND RESEARCH DEMONSTRATION

GLNPO's ambient monitoring activities include programs on a variety of environmental media such as the open lake, fish, and atmospheric toxics monitoring, and are described in Section 1.3. For these long-term projects, comparability of data over time is critical because many projects involve data sets representing more than 30 years. Comparability among other monitoring agencies, such as the Canadian government in the air toxics monitoring program, also is critical. For these programs, GLNPO stipulates development of quality system documentation that addresses all components of EPA QA/R-5. For GLNPO's fish monitoring program, sampling is conducted on a voluntary basis and therefore additional oversight is needed and must be addressed in quality system documentation.

7.2.1.2.6 POLLUTION PREVENTION AND ENVIRONMENTAL EDUCATION

GLNPO is involved in many environmental education and pollution prevention projects and the primary function often is to build stakeholder involvement and consensus for environmental initiatives. These projects also function to empower other organizations by providing information and training. In some cases, these projects involve compiling existing information to develop outreach materials for educating the public and organizations. These projects typically do not require as much documentation as many of the other GLNPO projects. The quality system documentation may focus on objectives of the project more than data quality. In general, quality management activities often are discussed in qualitative, as opposed to quantitative, terms. For some projects, an original proposal may serve to document the quality system sufficiently. In other cases, a quality management narrative that describes the objective of the project and the quality management activities that will be undertaken to ensure a successful project would suffice.

7.2.1.2.7 VOLUNTEER MONITORING

GLNPO administers several projects that involve volunteer monitoring. The quality system documentation for volunteer monitoring depends on the primary reason for collecting the information. In some cases, the primary reason is to educate and promote public stewardship of local environments. In these cases, quality system documentation may be a scaled-back version of EPA QA/R-5 and should focus on interactions with the individuals involved in monitoring and how they can be educated about the

environmental data they are gathering. In other cases, the monitoring is being conducted for a large study and the data will be used to characterize environmental conditions and make decisions. In these cases, standard operating procedures and training are of primary importance. The project may involve such quality management activities as a minimum performance test at the completion of volunteer monitoring training, to increase the confidence and quality of the data. Data collection forms are an important component of all volunteer monitoring activities and should be included in the systematic planning of projects and also in quality system documentation. Oversight of the project by qualified personnel is an important aspect of volunteer monitoring. Safety is of utmost importance in volunteer monitoring projects and must be considered in the documentation. For projects where a high level of data quality is needed, audits may be required at a high frequency to ensure proper procedures are being followed.

A series of fact sheets, guidance documents and methods for volunteer monitoring have been developed by EPA's Office of Wetlands, Oceans, and Watersheds (OWOW). GLNPO's QA Manager believes OWOW has done a very nice job of defining QA issues and considerations for quality system documentation. An OWOW website, <http://www.epa.gov/owow/monitoring/vol.html>, includes, The Volunteer Monitor's Guide to Quality Assurance Project Plans, in addition to a variety of other guidance documents and methods. GLNPO encourages individuals involved in volunteer monitoring projects to review these materials.

Table 7-2. Required Elements in a Quality Assurance Project Plan (QAPP)

Elements		Requirements
PROJECT MANAGEMENT		
A1	Title and Approval Sheet	Title and approval sheet.
A2	Table of Contents	Document control format.
A3	Distribution List	Distribution list for the QAPP revisions and final guidance.
A4	Project/Task Organization	Identify individuals or organizations participating in the project and discuss their roles, responsibilities and organization.
A5	Problem Definition/ Background	1) State the specific problem to be solved or the decision to be made. 2) Identify the decision maker and the principal customer for the results.
A6	Project/Task Description	1) Hypothesis test, 2) expected measurements, 3) ARARs or other appropriate standards, 4) assessment tools (technical audits), 5) work schedule and required reports.
A7	Data Quality Objectives for Measurement Dat	Decision(s), population parameter of interest, action level, summary statistics and acceptable limits on decision errors. Also, scope of the project (domain or geographical locale).
A8	Special Training Requirements/ Certification	Identify special training that personnel will need.
A9	Documentation and Record	Itemize the information and records that must be included in a data report package, including report format and requirements for storage, etc.

Elements		Requirements
MEASUREMENT/DATA ACQUISITION		
B1	Sampling Process Designs (Experimental Design)	Outline the experimental design, including sampling design and rationale, sampling frequencies, matrices, and measurement parameter of interest.
B2	Sampling Methods Requirements	Sample collection method and approach.
B3	Sample Handling and Custody Requirements	Describe the provisions for sample labeling, shipment, chain-of-custody forms, procedures for transferring and maintaining custody of samples.
B4	Analytical Methods Requirements	Identify analytical method(s) and equipment for the study, including method performance requirements.
B5	Quality Control Requirements	Describe routine (real-time) QC procedures that should be associated with each sampling and measurement technique. List required QC checks and corrective action procedures.
B6	Instrument/Equipment Testing Inspection and Maintenance Requirements	Discuss how inspection and acceptance testing, including the use of QC samples, must be performed to ensure their intended use as specified by the design.
B7	Instrument Calibration and Frequency	Identify tools, gauges and instruments, and other sampling or measurement devices that need calibration. Describe how the calibration should be done.
B8	Inspection/Acceptance Requirements for Supplies and Consumables	Define how and by whom the sampling supplies and other consumables will be accepted for use in the project.
B9	Data Acquisition Requirements (Non-direct Measurements)	Define the criteria for the use of non- measurement data such as data that come from databases or literature.
B10	Data Management	Outline the data management scheme including the path and storage of the data and the data record-keeping system. Identify all data handling equipment and procedures that will be used to process, compile, and analyze the data.
ASSESSMENT/OVERSIGHT		
C1	Assessments and Response Actions	Describe the assessment activities needed for this project. These may include DQA, PE, TSA, MSR/ PR/RR
C2	Reports to Management	Identify the frequency, content and distribution of reports issued to keep management informed.
DATA VALIDATION AND USABILITY		
D1	Data Review, Validation, and Verification Requirements	State the criteria used to accept or reject the data based on quality.
D2	Validation and Verification Methods	Describe the process to be used for validating and verifying data, including the chain-of-custody for data throughout the lifetime of the project.
D3	Reconciliation With Data Quality Objectives	Describe how results will be evaluated to determine if DQOs have been satisfied.

GLNPO added note: The above elements are the minimum requirements for a QAPP, and therefore, should be used during the QAPP development.

7.2.2 QA ANNUAL REPORT AND WORKPLAN

The Quality Manager may submit a QA Annual Report and Workplan (QAARWP) to GLNPO line management and EPA Quality Staff. This report summarizes the quality management activities for previous years and describes the activities planned for the coming year. The QAARWP generally includes:

- ▶ a general status of the quality management program including strengths, weaknesses, successes, and problems;
- ▶ an assessment of the adequacy of the QMP and recommended changes;
- ▶ a list of quality management training for GLNPO personnel;
- ▶ a list of quality system documentation and SOPs developed over the last year;
- ▶ a list of the major EICAAAs undertaken in the last year that require quality system documentation, the status of the documentation, including budgeting and time estimates for the development of outstanding documents;
- ▶ a list of the projects that were audited and reviewed in the preceding year; and
- ▶ a list of the major projects for which audits are planned for the coming year.

The report is submitted in conjunction with the GLNPO Team Workplans. In addition, the Quality Manager develops periodic reports that include categories for progress, problems and resolutions, reports, and a list of activities scheduled for the next period. These reports are presented to the management team during the monthly team briefings. The Quality Manager will immediately report any serious QA problems to line management as they arise. Serious matters requiring immediate attention will be reported directly to the GLNPO Office Director.

7.3 PEER REVIEW

EPA has a formal Peer Review Policy, described in the EPA Peer Review Handbook. In accordance with this policy, GLNPO requires that peer review be incorporated into the planning process for all *major, scientific or technical work products*. This documented, critical review is an in-depth assessment of the assumptions, calculations, extrapolations, alternate interpretations, methodology, acceptance criteria and conclusions pertaining to the major scientific or technical work product and of the documentation that supports this product. The determination that a scientific or technical product is "major" is based on whether it meets at least one of the following criteria:

- ▶ Does it support major regulatory decisions or policy/guidance of major effect?
- ▶ Does it establish a significant precedent, model or methodology?
- ▶ Does it address controversial issues?
- ▶ Does it focus on significant emerging issues?
- ▶ Does it have significant cross-Agency/inter-Agency implications?
- ▶ Does it involve a significant investment of Agency resources?
- ▶ Does it consider an innovative approach for a previously defined problem/process/methodology?
- ▶ Does it satisfy a statutory or other legal mandate for peer review?

GLNPO POs and the Quality Management Team can use the checklist, *GLNPO Required Peer Review Information*, (Appendix L) to assist them in complying with Agency peer review policy. Because GLNPO manages approximately 100-200 assistance agreements and contracts each year it is not practical to complete this checklist for all of these projects because most of them do not need peer review. The alternative approach that GLNPO utilizes meets the criteria in the Peer Review handbook and entails Project Inventory and Approval Forms (Appendices H and I) that are reviewed by the QA manager, who

recommends to GLNPO's Director whether the project needs quality system documentation or peer review. The peer review recommendation made by the QA manager is based on the questions posed in Appendix L and a final determination is made by the Director on approval of the package and corresponding documents. A new database, GLNPO's Projects Tracking Database (see section 2.6), which will be implemented in the last quarter of FY2002, will track the peer review status for each project. This database will include the contracts and in-house projects that are not subject to grant project inventory and approval forms and sign-offs. Peer review determinations will be sanctioned by the office.

Those projects requiring peer review, including those to be peer reviewed via a refereed, scientific journal, will be entered into the EPA Science Inventory which tracks national peer review products and science activities. The Peer Review Leader will be given GLNPO's checklist #2, or will fill out the appropriate fields in GLNPO's Projects Tracking Database. The progress of the peer review planning process can be tracked by entering comments or attaching documents to section 14 of the National Database, and when the peer review is completed the database manager will update the entry in the National Database. Those projects which do not need peer review, but are scientific or technical, are entered into the Science Activity section of the National Database. The project summaries for each fiscal year are added to the appropriate GLNPO science category, which are: Atmospheric Deposition Monitoring Program, Coastal Wetlands Monitoring and Indicator Development, Emerging Issues, Fish Contaminant Monitoring, Great Lakes Limnology Monitoring, Great Lakes Planktonic and Benthic Monitoring Program, Habitat Protection/Restoration, Invasive Species Program, Lake Michigan Mass Balance, Pollution Prevention, Sediment Assessment and Monitoring, and State of the Lakes Ecosystem Indicators.

7.4 HEALTH AND SAFETY ISSUES

The health and safety of project participants is of primary importance to GLNPO and health and safety issues must be addressed in the planning process for all GLNPO-funded EICAAs. For assistance agreements, GLNPO will address safety requirements within the special conditions sections of written agreements.

GLNPO has a designated Health, Safety, & Environmental Compliance Coordinator and Health and Safety Team who are responsible for managing health and safety issues at GLNPO. GLNPO has developed a comprehensive document outlining health and safety issues pertinent to GLNPO EICAAs titled, *Health, Safety, & Environmental Compliance Manual*. This manual was updated in May 2002. GLNPO conducts many EICAAs on the GLNPO research vessel R/V Lake Guardian and the R/V Mudpuppy. The manual specifies comprehensive requirements for medical monitoring and safety training for any GLNPO employee that will be working on our vessels. The R/V Lake Guardian and the R/V Mudpuppy also accommodate other EPA personnel, contractors, and researchers implementing GLNPO-funded EICAAs. The vessels each contain a copy of the current safety manual and GLNPO requires that all individuals working on the vessels review the manual. To facilitate this review, GLNPO provides training on the manual as part of its mandatory onboard training conducted each Spring prior to GLNPO's Water Quality Surveys. Safety inspections of the vessel occur annually or more frequently if hazardous situations are discovered. A report of the inspection is distributed to the GLNPO Health and Safety Team who then address any safety infractions. GLNPO's Health, Safety, & Environmental Compliance Coordinator is responsible for reviewing the *Health, Safety, & Environmental Compliance Manual* and revising it as needed to address all issues related to GLNPO EICAAs.

Office safety also is addressed in the GLNPO Health, Safety, & Environmental Compliance Manual as well as in the Region 5 Safety Manual (2000). GLNPO participates in the Region 5 evacuation procedures and has personnel identified to assist the Region 5 Safety Manager in an emergency. The Region 5 Safety Manager and the GLNPO Safety Manager annually inspect the GLNPO offices and vessels for hazardous conditions. The GLNPO Safety Manager will inform GLNPO employees of any specific hazards in their office space.

Section 8

Quality Implementation of Work Processes

Implementation of a quality system is as important as planning the system. For intramural and extramural projects, the GLNPO PO is responsible for ensuring that tasks supporting EICAAs are performed according to plan. GLNPO's processes for ensuring implementation of the quality system during EICAAs are detailed below.

8.1 INTRAMURAL ACTIVITIES

As described in the previous section, EICAAs require detailed, comprehensive planning and documentation of the planning process. These planning documents should detail operational tasks of an EICAA such as:

- | | |
|--------------------------------|--------------------|
| ▶ Field sampling | ▶ Sample analyses |
| ▶ Sample handling and shipping | ▶ Sample archiving |
| ▶ Sample preparation | ▶ Data reporting |

GLNPO ensures that these tasks are carried out according to plan by ensuring all relevant parties have copies of the planning documentation. It is the PO's responsibility to identify these relevant parties and distribute the planning documentation. The PO is also responsible for ensuring all involved parties understand the plan and their specific roles and responsibilities. This is often accomplished through a "kick-off" or "all-hands" meeting prior to the initiation of an EICAA. Because GLNPO often employs functional teams in the planning process and the individuals on the team will be subsequently involved in the tasks involved in the project, this provides an added benefit to GLNPO where the involved staff are fully informed of the purpose of the project and the project design.

For example, in support of GLNPO's base monitoring program, the monitoring team coordinates meetings of all involved staff in January or February as they develop their schedule for the year. These meetings include an assessment and subsequent revision of the QAPP for the survey and the SOP document, *Sampling and Analytical Procedures for GLNPO's Open Lake Water Quality Survey of the Great Lakes*, to capture small changes to the program. The schedules developed in the meetings are communicated to all parties involved in the survey through distribution of an "information package." The package contains a detailed survey schedule, sampling plan, and logistical information. In addition, onboard training is conducted prior to the survey. The training includes a review of health and safety issues, an overview of the survey schedule, a detailed review of SOPs, and information regarding location of current documents including all SOPs, planning documentation, and safety manuals. In this way, the PO ensures all involved parties are aware of the project purpose, plan, and their roles and responsibilities as outlined in the planning documents.

8.2 EXTRAMURAL ACTIVITIES

To ensure tasks are being performed in accordance with the project plan, the PO has regular communication with investigators. For example, for all GLNPO-funded EICAAs, the grantee prepares periodic (generally semi-annual or quarterly) reports on the status and progress of activities. For larger

scale or long-term EICAAs, the PO also conducts site visits, in accordance with government policy, to view tasks in progress. As needed, the PO is available to provide technical and logistical support to the investigator.

The investigator is required to submit SOPs with their quality system documentation or prior to initiating EICAAs. Any revisions to SOPs or quality system documentation must be approved by the PO *prior* to implementing the changes. The investigator is responsible for ensuring personnel are trained in all SOPs and laboratory and field operations according to the requirements in the quality system documentation. During review of the quality system documentation, the PO and Quality Management Team attempt to identify additional procedures that would benefit from development and implementation of SOPs. If additional SOPs are deemed to be necessary, the PO can request development and submittal of these SOPs prior to initiation of the EICAA. SOPs are discussed further in Section 2.4.

To assist POs in obtaining the required work products on schedule, the Quality Management Team provides reports to the PO listing outstanding work products, associated due dates, and the review and approval status of these reports. As necessary, the Quality Management Team assists the PO with implementing the *Protocol to Address Missed Requirements* (Appendix M). This protocol is discussed in detail in Section 7.

For extramural projects, GLNPO's relationship to external parties is maintained through the PO. The PO is the only person who has the power to accept or reject the product from an EICAA that is being funded by GLNPO. Although the Quality Management Team is intimately involved in the EICAA, they function to assist the PO in effectively implementing the EICAA. For example, all correspondence regarding the project is addressed to the PO, who must then communicate the information to the grantee. The Quality Management Team does not work directly with the funded party without the PO's involvement. Responsibility of the PO for implementing the system and they have final authority for determining activities of the grantee.

8.3 COMMUNICATION

Due to the multitude of external parties involved in GLNPO projects, communication is critical to the success of GLNPO EICAAs and accomplishment of the mission. The Quality Manager attends monthly meetings with GLNPO management and presents a written report on the progress and status of quality system activities for all ongoing EICAAs. In most cases, the Quality Management Team will copy Management Advisors on all internal and external communications for projects under their responsibility. Communication between the Quality Management Team and all GLNPO staff also is fostered through the quality system training provided by the Team.

8.4 DISPUTE RESOLUTION

Implementation of quality management activities may sometimes result in disagreements among involved parties. When these disputes occur, resolution will be sought at the lowest management level. GLNPO staff will attempt to resolve the dispute through discussion and negotiation. Final resolution will be made by GLNPO's Director when negotiations do not resolve the issue.

Section 9

Quality Assessment and Response

Quality assessments are used to determine the effectiveness of a quality system in meeting its goals — in GLNPO's case, in ensuring that environmental information is of adequate quality for its intended use. An assessment is a formal evaluation of performance relative to pre-determined standards. Once an evaluation is conducted and documented, a response is implemented that provides corrective actions to improve performance where necessary. A variety of tools are available to assess environmental information collection activities including: audits, data quality assessments, quality systems audits, peer reviews, technical reviews, performance evaluations, and technical systems audits. These assessments are the principal means used by EPA to determine compliance and to control systems in a real-time manner to improve performance. This section describes GLNPO's use of these assessment tools.

9.1 QUALITY SYSTEMS AUDITS AND TECHNICAL SYSTEMS AUDITS

Quality systems audits (QSAs), previously termed management systems reviews, are on-site evaluations by internal or external parties to determine if the organization is implementing a satisfactory quality management program. They are used to determine the adherence to the program, the effectiveness of the program, and the adequacy of allocated resources and personnel to achieve and ensure quality in all activities. Internal QSAs are conducted by GLNPO senior management. GLNPO-funded entities also may undergo QSAs lead by GLNPO's Quality Manager. External QSAs are conducted by EPA Quality Staff to determine compliance of GLNPO's program with this QMP. The QSA includes reviews of:

- ▶ adherence to the GLNPO quality management plan,
- ▶ procedures for developing project quality objectives and other acceptance criteria,
- ▶ procedures for planning EICAAs,
- ▶ procedures for developing and approving quality system documentation,
- ▶ the quality of existing quality system documentation,
- ▶ procedures for developing and approving standard operating procedures (SOPs),
- ▶ procedures, criteria, and schedules for designing and conducting audits,
- ▶ tracking systems for ensuring that the quality management program is operating and that corrective actions disclosed by audits have been taken,
- ▶ the degree of management support,
- ▶ responsibilities and authorities of the various line managers and the Quality Manager for carrying out the quality system,
- ▶ the level of financial resources and personnel devoted the implementing the quality system, and
- ▶ existence of appropriate quality system documentation and its conformance with the requirements of the quality management plan.

To achieve the objectives of a QSA, the review should be conducted by an individual somewhat independent of the organization, but still with a "stake" in seeing improvement. Because GLNPO cooperates with many agencies, an individual from one of these agencies could lead an internal QSA. The leader could then build a review team composed of individuals from GLNPO senior management that would assist in the planning, scheduling, and implementation of the review. Prior to the audit, the review team should develop an audit plan that defines the scope, purpose, and details of the review as discussed in Section 9.5.

The Quality Management Team will coordinate periodic QSAs of specific GLNPO functional teams, depending on the number and importance of the projects being conducted by a Team. For GLNPO's base monitoring program, the Quality Management Team will conduct an QSA on at least one component of the program every year (e.g., limnology, fish monitoring, atmospheric monitoring, etc.) and more frequently if serious deficiencies are identified. The review should occur between the months of March and April, at the start of the Spring Survey.

Results of all QSAs coordinated by GLNPO are presented in reports to GLNPO management, the Quality Manager, and EPA Quality Staff. The format for these reports is discussed in Section 9.5. For all identified deficiencies, the review teams will develop proposed corrective actions and will discuss them in the report. These corrective actions will become goals as part of the Quality Manager's performance appraisal. In addition, the Quality Manager will detail the progress on these corrective actions at management meetings, during Quality Manager performance reviews, and in subsequent QAARWPs.

Technical systems audits (TSAs) are qualitative on-site evaluations of all phases of an EICAA (i.e., sampling, preparation, analysis). These audits can be performed prior to or during the data collection activity, in order to evaluate the adequacy of equipment, facilities, supplies, personnel, and procedures that have been documented in the quality system documentation. Because a TSA is most beneficial at the beginning of a project, GLNPO will schedule audits at the initiation phase of an EICAA, when possible. GLNPO will perform a QSA, site visit, or TSA for the most high-profile EICAA's (i.e., those that support an important decision). The number and frequency are dependent on the length of the project, the importance of the project objectives, and the evaluations of prior audits. GLNPO will conduct TSAs on two or more GLNPO grants or contracts that involve EICAAs each year. Selection of these grants and contracts will be proposed by the Quality Manager and sanctioned by the Quality Management Team Management Advisor (GLNPO's Director).

GLNPO's value-added assessments focus on improvement of the data collection process through direct involvement of the technical team members in the assessment response.

Audits will be scheduled by the PO and tracked by the Quality Manager. The Quality Manager can assist in facilitating audits at the request of the PO. In addition, the Quality Manager can participate in audits at any time, to evaluate auditing procedures. The PO, in conjunction with the Quality Management Team, is responsible for developing an audit plan (section 9.5) and documenting audit results (section 9.7).

9.2 PERFORMANCE EVALUATIONS

Performance evaluations (PEs) are a means of independently evaluating data quality and the variability associated with the overall measurement system or a distinct phase of the measurement system. This is accomplished through the analysis of samples of known composition and concentration. These samples can be introduced into the measurement system as blind samples where the identity and the concentration are unknown to the analyst. These samples can be used to evaluate bias and precision and to determine whether DQOs or MQOs associated with a given project have been satisfied. PEs also can be used to determine inter- and intra-laboratory variability over the course of long-term projects, and to evaluate laboratories prior to contract awards.

PEs are required for projects involving important decisions or where multiple parties are involved in data collection and data comparability is an issue. At times, PE samples may be of interest to a PO but appropriate reference material from reliable sources may not be available. If time permits, the PO, in conjunction with the Quality Management Team, can coordinate development of reference samples from a bulk source. The samples are characterized by a laboratory, independent of the project, through analysis of a statistically valid number of replicates and then used as reference material. GLNPO participates in PE programs that apply to its EICAAs and provide information regarding data quality. For example, GLNPO participates in several PE programs coordinated by the National Laboratory for Environmental Testing in Ontario. GLNPO distributes information regarding pertinent PE programs to grantees, states, and other involved parties and encourages participation. As part of the systematic planning, POs should consider the use of PE samples.

9.3 PROJECT ASSESSMENTS

In order to conduct efficient audits, POs in conjunction with the Quality Management Team should thoroughly plan the audit and document the plan. The audit plan document is not a major undertaking and in most cases will be a one page table or report. However, the document represents thoughtful and concise planning for an efficient and successful audit. The audit plan should be made available to the organization audited, with adequate lead time to ensure that appropriate personnel and documents are available for the audit. An audit plan for any type of audit will typically include the items listed in Table 9-1.

Table 9-1. Items to be Included in Project Assessments

Item	Description
Project title	GLNPO project title
Audit number	Year and number of audit can be combined; 2001-1, 2001-2
Date of audit	Date audit is scheduled
Scope	Establishes the boundary of the audit and identifies the groups and activities to be evaluated. The scope can vary from general overview, total system, to part of system, which will effect the length of the audit.
Purpose	Why the audit is being conducted and what the audit should achieve.
Standards	Standards are the criteria against which performance is evaluated. These standards must be clear and concise and should be used consistently when auditing similar facilities or procedures. The use of audit checklists is suggested to assure that the full scope of an audit is covered. An example checklist for an analytical laboratory audit can be found in Appendix P.
Audit team	Team leader and members and their affiliation.
Auditees	People that should be available for the audit from the audited organization. This should include the Program Manager, Principal Investigator, organizations QA Representative, and other management, and technicians as necessary.
Documents	Documents that should be available for the audit to proceed efficiently. Too often documents are asked for during an audit, when auditors do not have the time to wait for these documents to be found. Documents could include QMPs, QAPPs, SOPs, GLPs, control charts, raw data, QC data, previous audit reports, etc.
Timeline	A timeline of when organizations (auditors/auditees) will be notified of the audit for efficient scheduling and full participation of all parties. The timeline also may include the schedule for the opening briefing, data collection, exit briefing, and draft report or other product.

9.4 ASSESSMENT IMPLEMENTATION

After the audit plan has been developed, the auditee is notified prior to conducting the on-site visit, to inform the auditee about the audit including its scope, purpose, and logistics. During this initial contact, certain information can be requested such as the auditees organizational structure, SOPs, GLPs, control charts, etc., that will help to efficiently implement the audit. Mutually acceptable audit dates should be identified so that the appropriate staff are available during the audit period.

During the actual audit, there should be an initial interview with the audit team and the auditees, in order to restate the scope and purpose of the audit, and develop a detailed schedule that is acceptable to all involved parties. The schedule should include a list of the operational phases of the EICAA that will be observed and time for debriefing activities.

During the observation phase of the audit, one must be aware of one's own perceptions (a good job to one auditor may be a sloppy job to another). Three concepts (Arter, 1989) to consider in order to persuade the audited organization that the auditor's perception of the facts is useful include:

- ▶ *Present items and facts that will satisfy the needs of the audited and auditing organizations. Make a contribution. Show how the facts affect the product or service.*
- ▶ *Ignore or downplay mildly disturbing things. Do not nitpick. Strive to answer the "So what?" response.*
- ▶ *Pay attention to significant things. Chronic or persistent problems and weaknesses, along with trends, will get the auditee's attention.*

**The Six Steps to the Basic Observation Interview
(as explained by Arter, 1989)**

- ① Put them at ease.** Give the auditee an opportunity to size you up and lower the natural sense of anxiety.
- ② Explain your purpose.** Tell the auditee what you want and why you are asking the questions. Most people will express a desire to share information once it is known why it is wanted.
- ③ Find out what they are doing.** Use open-ended questions (e.g., "what do you do as soon as you get the sample; and then what happens.") The checklist described in Appendix P can then be used during the auditee's response to fill in the "yes/no" answers.
- ④ Analyze what they are doing.** Once you have heard the words, analyze what they mean. You may want to repeat the process and "think out loud" which will force you to put the facts in perspective and in a logical arrangement.
- ⑤ Make a tentative conclusion.** Conclusions of that phase of the EICAA can be made. If the initial analysis indicates that all is well, let the person know; they will continue to perform well with recognition from an outsider. If there is a deficiency, give the auditees an opportunity to produce additional factual evidence to show that you have made the error.
- ⑥ Explain your next step.** Conclude the discussions and let the person know what's next. It is important to remember that people want to know: (1) how they did in the interview, and (2) whether they are finished.

The six steps listed below are presented in Arter's book, *Quality Audits for Improved Performance* (1989) along with additional details of all phases of an audit. A reference copy is available from the GLNPO Quality Manager and is a suggested source of good information.

9.5 DATA QUALITY ASSESSMENTS

A data quality assessment (DQA) is used to evaluate the quality of specific data and determine if this quality satisfies the stated project objectives of an EICAA. POs and the Quality Management Team can use the guidance document, EPA QA/G-9, *Guidance for the Data Quality Assessment Process: Practical Methods for Data Analysis* developed by EPA Quality Staff to assist them assessing data quality.

Data quality assessments are generally conducted on the second TSA, at the completion of an EICAA as part of a QA report, or at the request of a PO when concerns about data quality are identified.

Based on TSA reports, the Branch Chief or the Quality Manager may suggest a DQA to the PO. The PO is responsible for determining the need for a DQA and will be responsible for conducting this assessment and developing subsequent reports. The GLNPO Quality Manager can assist in facilitating the assessment as necessary.

Data quality assessments also can be made by conducting data review and verification. These reviews typically focus on the QA data collected with the routine field data. Examples of QA analysis checklists are provided in Appendix R.

In support of the Lake Michigan Mass Balance (LMMB) Study, GLNPO has developed “state-of-the-art” data quality assessment approaches. For the study analytes, GLNPO determined quantitative estimates of data quality in terms of three attributes: sensitivity, precision, and bias. In addition, GLNPO developed a novel approach to assessing data quality, the percent variability due to sampling and analytical measurement uncertainty. These estimates are described below.

Sensitivity The detection limit for each data set was estimated by the principal investigator. The types of detection limits vary among investigators, although a commonly used approach in LMMB was EPA’s MDL (described at 40 CFR part 136, Appendix B that involves analysis of seven replicate samples of known concentration). Sensitivity for each data set is presented as a percent of field sample results above and below the detection limit.

Precision Precision was estimated through statistical analysis of analytical results for field and laboratory duplicate samples. System precision, a measure of the precision for the entire sampling and analytical procedure, was estimated through comparison of analytical results obtained for routine field samples and their associated field duplicates. Analytical precision, a measure of the precision of the laboratory analytical component of the system, is a subset of the system precision, and was estimated through comparison of analytical results obtained for routine field samples and their associated laboratory duplicates.

Bias Bias was estimated through statistical analysis of analytical results for laboratory-spiked routine field samples. System bias, a measure of the bias of the entire sampling and analytical procedure, can be estimated through analysis of samples that have been spiked in the field. Analytical bias, a measure of the bias of the laboratory analytical component of the system, can be estimated through analysis of laboratory-spiked environmental or blank samples.

*Percentage of variability due to sampling
and analytical measurement uncertainty*

The percentage of variability due to sampling and analytical measurement uncertainty is estimated as the proportion of variability among all RFS results that can be attributed to sampling and analytical measurement uncertainty. This measure is estimated as the mean variance between field duplicate pairs as a proportion of the variance among all RFS samples.

The quantitative estimates described above reflect data quality for a given entire data set produced by a single laboratory. Study modelers have requested an interval estimate for single study results. GLNPO is currently developing approaches to determine these interval estimates. GLNPO plans to continue to develop approaches to assessing data quality and apply these approaches to all EICAAs.

9.6 ASSESSMENT REPORTING

At the completion of an audit, the audit team will meet with auditees to discuss the results of the audit and the next steps of the process. Positive and negative aspects of the EICAA will be discussed between the audit team, management of the area audited, and, if necessary, technical personnel performing the measurement activity. The review team should provide copies of the draft audit summary and findings to all in attendance. The review team will discuss with the auditees, all necessary actions needed to improve the measurement system.

The PO is responsible for reporting results from TSAs, DQAs, and PEs, even when the PO is not the review team leader for the audit. For QSAs, the review team leader or an appointed designee is responsible for preparing the report. These reports generally include:

- ▶ audit title and number and any other identifying information;
- ▶ audit team leaders, audit team participants and audited participants;
- ▶ background information about the project, purpose of the audit, dates of the audit, particular measurement phase or parameters that were audited, and a brief description of the audit process;
- ▶ summary and conclusions of the audit and corrective action requirements; and
- ▶ attachments or appendices that include all audit evaluation forms and audit finding forms.

A report should be completed within five working days of completion of an audit. The Quality Manager and PO review TSA, DQA, and PE reports and document their review and approval through an approval signature. The report is then filed with the Quality Manager. For QSAs, the audit team leader and GLNPO Director review the reports and provide the approval signatures. The reports are filed with the Director and Quality Manager. It is the responsibility of the review team leader to forward audit reports to the appropriate project participants. Audit reports have restricted distribution in order to foster constructive working relationships. When significant concerns are identified during an audit, GLNPO's Quality Manager or Director will schedule a meeting to address these concerns with the appropriate parties.

9.7 RESPONSE ACTIONS

As mentioned above, the audit reports are discussed with the audited organization specifically noting the corrective actions necessary to rectify and control the situation. Line management may be requested to assist in problem resolution. For each audit finding, an audit finding response form will be developed to track corrective actions. An example audit finding response form is provided in Appendix Q. These forms will be included in the audit file retained by the Quality Manager. The PO (for TSAs, DQAs, PEs, and QSAs of other organizations) or the GLNPO Director (for QSAs of GLNPO) are responsible for ensuring compliance with the corrective actions. If major deficiencies are found, follow-up audits are often required.

Section 10

Quality Improvement

GLNPO's quality policy focuses on four operating principles: assistance, flexibility, value-added, and *continuous improvement*. This QMP details GLNPO's quality system policy and processes, many of which facilitate improvement of GLNPO EICAAs. For example, monthly management meetings, quality system training, data quality assessments, and peer review activities provide opportunities to identify areas for improvement that can be addressed in subsequent projects. GLNPO's quality system is designed to facilitate identification and communication of these areas of improvement to all GLNPO staff through meetings, training, and Quality Management Team reports. This section describes GLNPO's process for realizing continuous improvement.

10.1 PROGRAM REVIEW

This QMP is approved by the GLNPO Director and all GLNPO Branch Chiefs, thereby demonstrating their commitment to GLNPO's quality system. GLNPO management is responsible for ensuring that GLNPO staff follow the guidelines of the quality system as documented in this QMP. This is facilitated through regular quality system training, Quality Management Team monthly reports on the status of quality system activities, and maintenance of a central library that contains GLNPO quality system documents and Agency guidance and requirements documents. GLNPO's quality system is constantly being evaluated for effectiveness. Line management and the Quality Manager meet quarterly to discuss adherence to the QMP and to identify where improvements can be made. For any major quality system deficiencies, the Quality Manager will develop proposed corrective action, implement the action, and finally assess its implementation. The Quality Manager will summarize these meetings including the areas for improvement and corrective actions in a quarterly report that is placed on GLNPO's LAN in the QA directory. These reports also will be included in the QAARWP.

The input to management review shall include information on:

- results of audits,
- stakeholder feedback on the quality system,
- staff competence,
- process performance, and
- the status of preventive and corrective actions.

Management should always seek positive methods for ensuring adherence to policy; however, management must implement corrective action procedures for staff that do not adhere to GLNPO or EPA policy (e.g., obtaining approval of quality system documentation *prior* to implementation of an EICAA). If staff members continuously disregard the policy, management should include this assessment in the individual's performance evaluations.

The Quality Manager will review this QMP each year to determine if the document is relevant to GLNPO's mission and reflects current procedures. Sections will be modified to address GLNPO's evolving program and changing needs. GLNPO's quality system and this QMP also will be reviewed as needed when changes in Agency policy or guidance occur. Revision of the QMP will be noted by the change in revision number and the date of the revision included in the header information and in the

Table of Contents. All revisions will be reviewed and approved by GLNPO's Director, Branch Chiefs, and EPA Quality Staff before implementation. Upon approval, the QMP will distributed to all GLNPO staff, along with a summary of the revisions

As discussed in Section 9, GLNPO invites Quality Staff to review the GLNPO's quality system at any time or at a minimum of every two years. For all areas where deficiencies exist, the GLNPO Quality Manager and line management will develop action plans for any deficiencies and inform EPA Quality Staff of their progress to rectify these situations.

10.2 PROJECT REVIEWS

As mentioned above, a variety of tools that are implemented as part of GLNPO's quality system facilitate improvement. Technical audits, peer reviews, and data quality assessments can improve the quality for long-term EICAAs and for subsequent projects. In addition, to increase the effectiveness of its EICAAs, GLNPO will conduct "wrap-up" meetings at the conclusion of as many EICAAs as possible. These meetings should include as many project participants as practical. The meetings provide an opportunity to review the quality system documentation to determine how the plan could be improved, and how similar ongoing projects may benefit from addressing these areas for improvement. Preliminary data quality assessments should be available to determine whether the quality system was successful in controlling data quality to an acceptable level. The meetings serve to focus project planners and participants on areas for improvement in all aspects of the EICAA including planning, field and laboratory procedures, and appropriateness of the quality system. This project review will assist project planners in identifying preventive actions that can be included in future EICAAs. The Quality Management Team will document these meetings and maintain them on the GLNPO LAN so that these "lessons learned" can be applied to all subsequent EICAAs where applicable.

GLNPO shall continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive action, and management review.

References

The EPA Quality Staff developed a series of documents describing the various requirements of the overall EPA quality system as well as a series of guidance documents that describe how the system can be implemented by EPA and by external organizations, including contractors and grantees. Many of these documents are cited in the body of this quality management plan. All of the documents are available from the Quality Staff web site in PDF format. The current uniform resource locator (URL) for that web site is: www.epa.gov/quality

The Quality Staff also are working on a variety of new documents and revisions to existing ones, and the reader is encouraged to check the web site above frequently for the latest available information.

Requirements Documents

All of the documents that describe formal quality requirements for EPA organizations are defined "EPA Directives," and are policy documents. These include:

- EPA Order 5360.1 A2, May 2000, *Policy and Program Requirements for the Mandatory Agency-wide Quality System*. This document describes the Quality requirements for EPA organizations that produce environmental data.
- EPA Manual 5360 A1, May 2000, *EPA Quality Manual for Environmental Programs*. This document describes the specifications for satisfying the mandatory quality system defined in EPA Order 5360.1

Additional requirements documents apply to both EPA and external organizations. They are designated with the letter "R" followed by a number. The documents that are available in final form at this time are:

- EPA QA/R-2, March 2001, *EPA Requirements for Quality Management Plans*. QA/R-2 is the policy document containing the specifications and requirements for Quality Management Plans.
- EPA QA/R-5, March 2001, *EPA Requirements for Quality Assurance Project Plans*. QA/R-5 replaces the 1980 document QAMS-005/80. This external policy document establishes the requirements for QA Project Plans prepared for activities conducted by or funded by EPA. It is intended for use by organizations having extramural agreements with EPA.

Guidance Documents

The Quality Staff have prepared a number of guidance documents that can assist in the development and implementation of a suitable quality system for both EPA and non-EPA organizations. The guidance documents are designated with the letter "G" followed by a number. The documents that are available in final form at this time are:

- EPA QA/G-4, August 2000, *Guidance for the Data Quality Objectives Process*. QA/G-4 provides guidance to help organizations plan, implement, and evaluate the Data Quality Objectives (DQO) process, a systematic planning process for environmental data collection. It has a focus on environmental decision-making for regulatory and enforcement decisions. The guidance presents a step-by-step description of the DQO process.

- EPA QA/G-4D, September 1994, *Data Quality Objectives Decision Errors Feasibility Trials (DEFT) Software*. QA/G-4D provides guidance for using the Decision Error Feasibility Trials (DEFT) software to help organizations plan, implement, and evaluate the Data Quality Objectives (DQO) process. The guidance presents a step-by-step description of the use of the PC-based DEFT software DQO process.
- EPA QA/G-4HW, January 2000, *Guidance for the Data Quality Objectives Process for Hazardous Sites*. QA/G-4HW provides guidance to help organizations plan, implement, and evaluate the statistics-based Data Quality Objectives (DQO) process as applied to hazardous waste sampling activities. The guidance will present a step-by-step description of the DQO process and its application to environmental remediation and waste management activities.
- EPA QA/G-5, February 1998, *Guidance on Quality Assurance Project Plans*. QA/G-5 provides guidance to help organizations develop Quality Assurance Project Plans that will meet EPA expectations and requirements. The document provides a linkage between the DQO process and the QAPP. It contains tips, advice, and case studies to help users develop improved QAPPs.
- EPA QA/G-5M, April 2002, *Guidance for Quality Assurance Project Plans for Modeling*, peer review draft. QA/G-5M discusses issues to be addressed in QA Project Plan elements in the context of data use on modeling, emphasizing systematic planning, the use of existing data, hardware and software configuration issues for modeling, and the graded approach.
- EPA QA/G-6, March 2001, *Guidance for the Preparation of Operating Procedures for Quality-Related Operations*. QA/G-6 provides guidance to help organizations develop and document standard operating procedures (SOPs). The document contains tips, advice, and case studies to help users develop improved SOPs.
- EPA QA/G-7, January 2000, *Guidance on Technical Assessments for Environmental Data Operations*. QA/G-7 provides guidance to help organizations plan, conduct, evaluate, and document technical assessments for their programs.
- EPA QA/G-9, July 2000, *Guidance for the Data Quality Assessment Process: Practical Methods for Data Analysis*. QA/G-9 provides guidance for planning, implementing, and evaluating retrospective assessments of the quality of the results from environmental data operations. Data quality assessment is a statistically-based, quantitative evaluation of the extent to which a data set satisfies the user's needs. This document is aimed at the project managers who are responsible for conducting the environmental data operations and assessing the usability of the results.
- EPA QA/G-9D, December 1997, *Data Quality Evaluation Statistical Toolbox (DataQUEST)*. QA/G-9D provides guidance for planning, implementing, and evaluating retrospective assessments of the quality of the results from environmental data operations using the PC-based software, DataQUEST.
- EPA QA/G-10, December 2000, *Guidance for Determining Quality Training Requirements for Environmental Data Operations*. QA/G-10 provides guidance to help organizations determine and develop program-specific quality system training for all levels of management and staff.
- No number, July 1999, *Guidance on Quality Assurance Project Plans for Secondary Research Data*. Example Quality Assurance Project Plan requirements for secondary research data developed by the QA Managers in EPA's National Risk Management Research Laboratory.

EPA QA/G-0	“EPA Quality System Description” November 1997
EPA QA/G-3	“Guidance for the Management Systems Review Process “ January 1994
Arter, D.R. 1989.	“Quality Audits for Improved Performance” ASQC Quality Press, Milwaukee, Wisconsin. 93 pp.
Byers, G.E. 1991.	“Quality Assurance Program in Monitoring and Research Strategy For Forests” EPA 600/4-91/012. U.S. Environmental Protection Agency. Las Vegas, Nevada.
EPA Order 5360.1 A2	“Policy and Program Requirements for the Mandatory Agency-wide Quality System” U.S. Environmental Protection Agency May 2000
Proposed New EPA Order	Policy for Competition in Assistance Agreements, July 15, 2002
ISO 9001:2000	“Quality Management Systems – Requirements”, International Organization for Standardization”, 2000.
Simes, G. F. 1989.	“Preparing Perfect Project Plans” EPA/600/9-89/087. U.S. Environmental Protection Agency, Cincinnati, Ohio.
Taylor, J.K. 1987.	“Quality Assurance of Chemical Measurements” Lewis Publishers, Chelsea, Michigan. 328 pp.

Glossary

bias	the level of agreement between an observed value and the "true" value of a characteristic
blind sample	a reference sample submitted to the analyst in such a manner that the sample is known as a reference sample but its concentration is unknown
comparability	the similarity of data from different sources included in a given set of data and the similarity of methodologies from related projects across the regions of interest
completeness	the quantity of data that is successfully collected with respect to the amount intended in the experimental design
data quality objective	user-defined criteria established for each parameter to evaluate usability of data
environmentally-related data	Any laboratory or field data gathering activity or investigation involving the determination of chemical, physical, or biological factors related to the environment.
measurement quality objective	critical level which, if exceeded, is considered to append additional and possibly unacceptable, measurement uncertainty to the corresponding data
overall data uncertainty	confounded population and measurement uncertainty occurring in a sample
precision	the level of agreement among multiple measurements of a characteristic
project	An organized undertaking or specified unit of investigation involving environmentally related measurements
quality assurance	The total integrated program for assuring the reliability of monitoring and measurement data.
quality control sample	any sample utilized by the analyst to check measurement conditions, whose measurement is expected to fall within specific acceptance criteria or control limits
representativeness	the degree to which the data collected accurately represents the population of interest
uncertainty	a measure of imprecision, bias, or other sources of variability in a given value

validation	the process of determining the legitimacy of data for its state purpose, involving internal consistency checks for outlier removal and definition of levels of confidence
variability	imprecision about a specific characteristic